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(12) **United States Patent**
Greenberg et al.

(10) **Patent No.: US 9,125,733 B2**
(45) **Date of Patent: Sep. 8, 2015**

(54) **BRANCHED VESSEL ENDOLUMINAL DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1555 days.

(21) Appl. No.: **12/174,451**

(22) Filed: **Jul. 16, 2008**

(65) **Prior Publication Data**

US 2009/0043377 A1 Feb. 12, 2009

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/403,605, filed on Apr. 13, 2006, now Pat. No. 7,407,509, which

(Continued)

(51) **Int. Cl.**

A61F 2/06 (2013.01)
A61F 2/07 (2013.01)
A61F 2/89 (2013.01)

(52) **U.S. Cl.**

CPC ... ***A61F 2/07*** (2013.01); *A61F 2/89* (2013.01); *A61F 2002/061* (2013.01); *A61F 2002/065* (2013.01); *A61F 2002/067* (2013.01); *A61F 2002/068* (2013.01); *A61F 2002/075* (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61F 2/06
USPC 623/1.35, 1.1, 1.16, 1.15; 606/198
See application file for complete search history.

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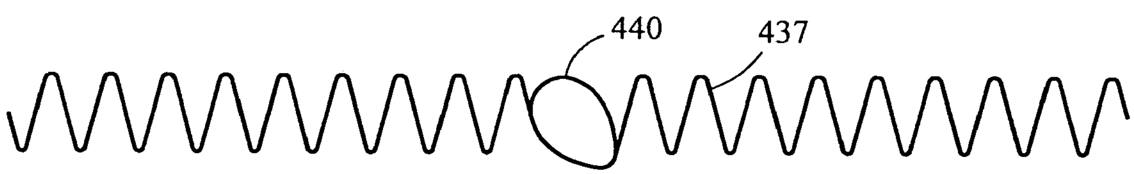
(57) **ABSTRACT**

An endoluminal prosthesis comprises a prosthetic trunk having a trunk lumen and a trunk wall, a first prosthetic branch having a first branch lumen and a branch wall, and a second prosthetic branch having a second branch lumen. The first branch lumen and the second branch lumen are both in fluid communication with the trunk lumen through the trunk wall and the second branch lumen is in fluid communication with the first branch lumen through the branch wall. Additional devices, systems, and methods are disclosed.

13 Claims, 41 Drawing Sheets



Related U.S. Application Data

is a continuation-in-part of application No. 10/756,803, filed on Jan. 13, 2004, now Pat. No. 7,105,020.

(60) Provisional application No. 60/439,923, filed on Jan. 14, 2003, provisional application No. 60/478,107, filed on Jun. 11, 2003, provisional application No. 60/510,636, filed on Oct. 10, 2003, provisional application No. 60/671,410, filed on Apr. 13, 2005.

(52) **U.S. Cl.**
CPC . *A61F 2230/0013* (2013.01); *A61F 2230/0067* (2013.01); *A61F 2250/0063* (2013.01)

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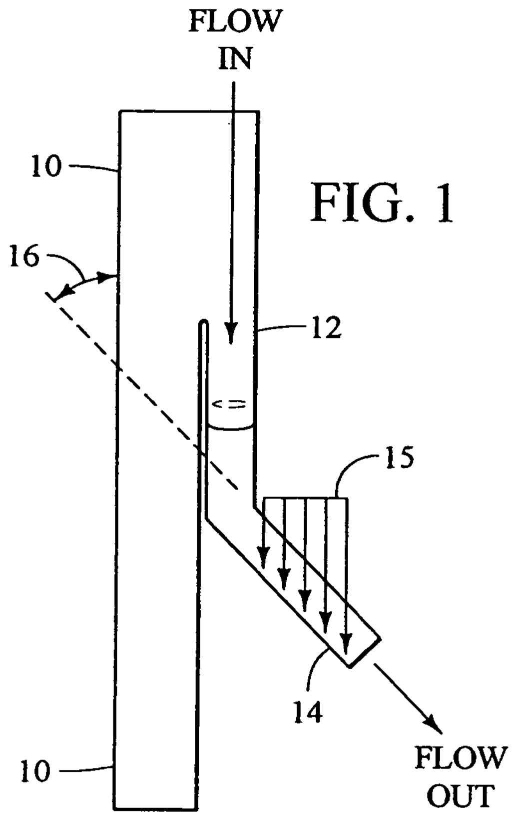

FIG. 1

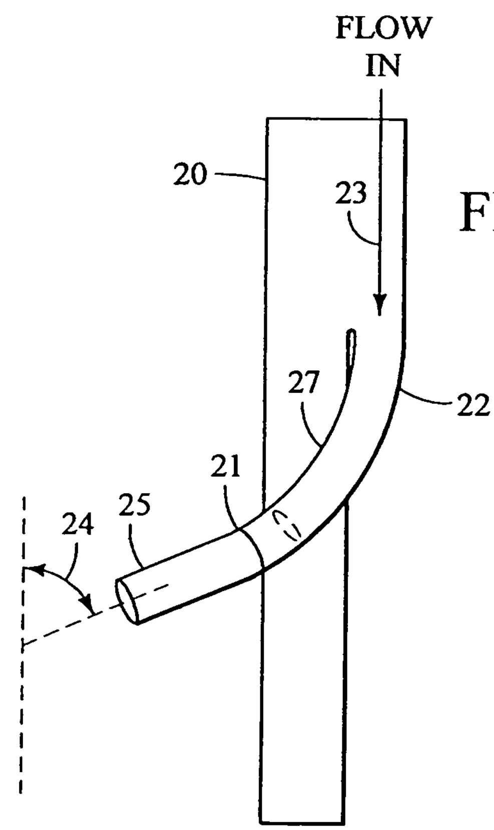

FIG. 2

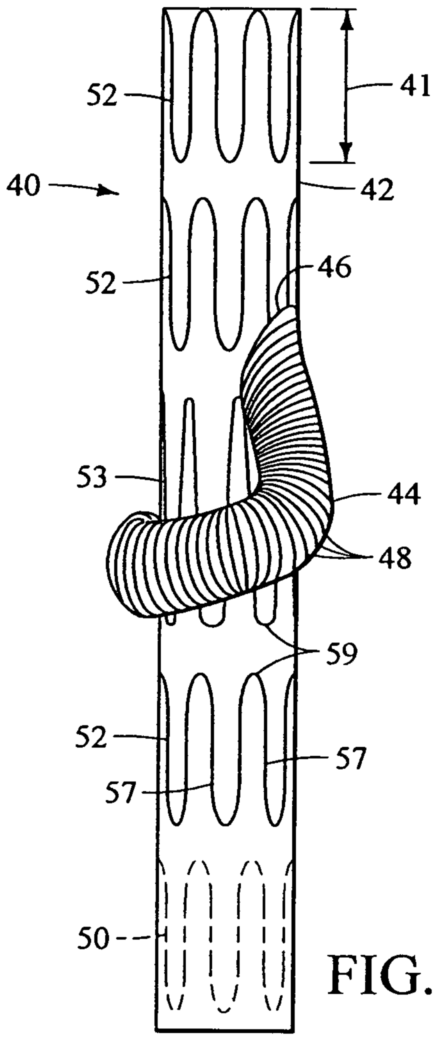

FIG. 3a

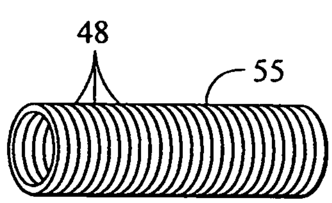

FIG. 3c

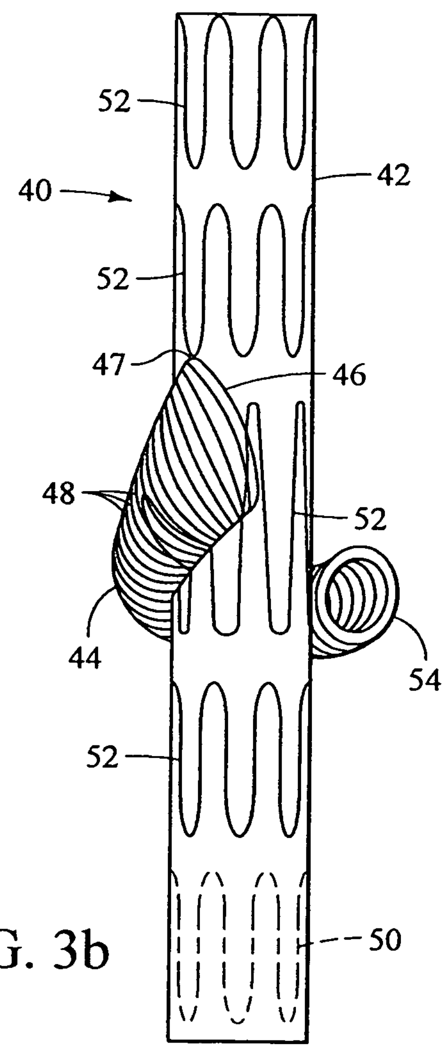

FIG. 3b

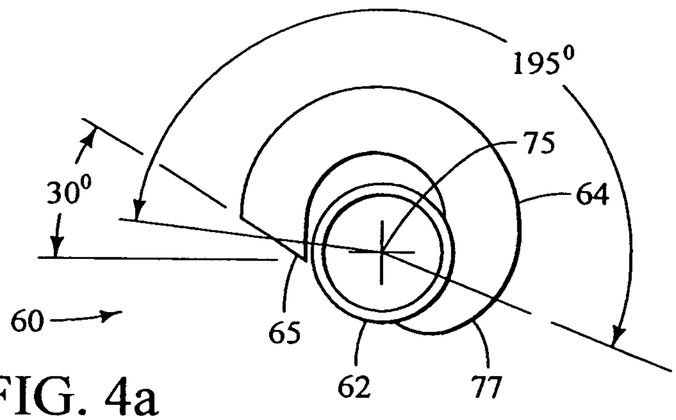

FIG. 4a

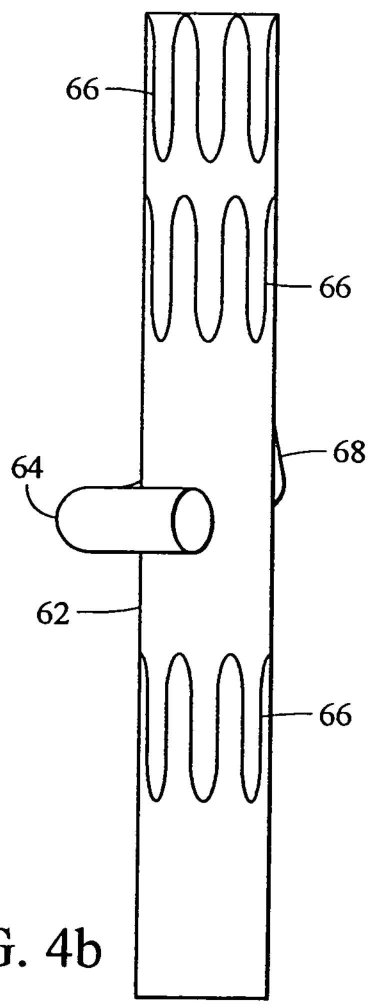

FIG. 4b

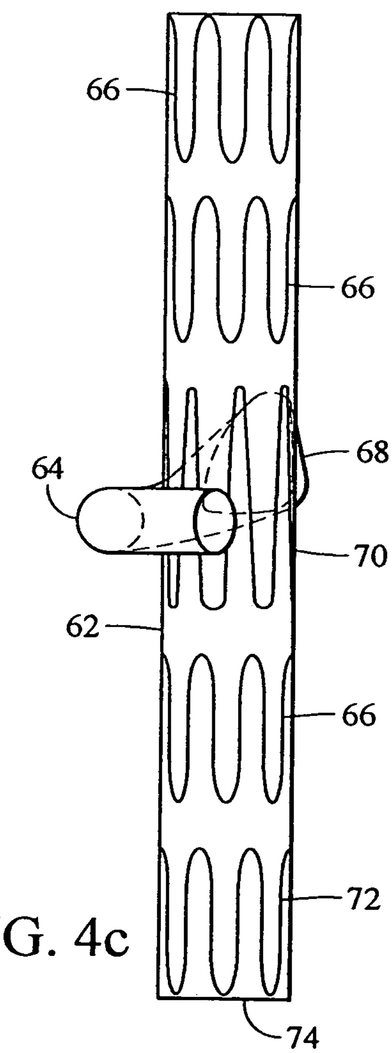

FIG. 4c

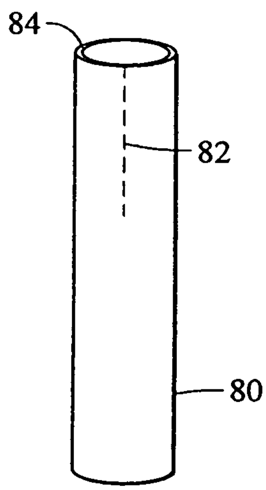

FIG. 5a

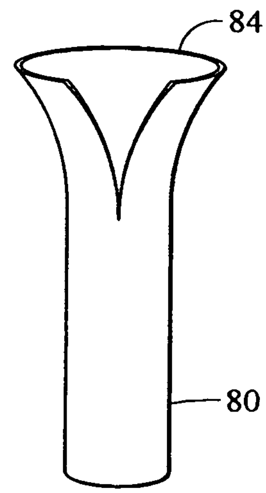

FIG. 5b

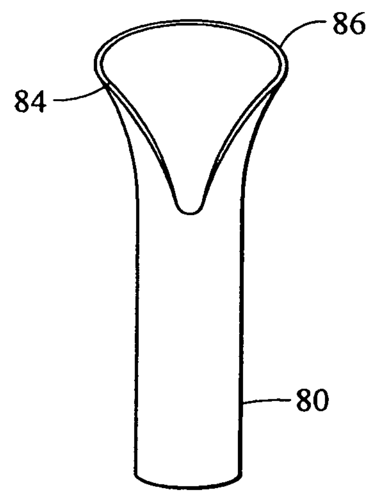

FIG. 5c

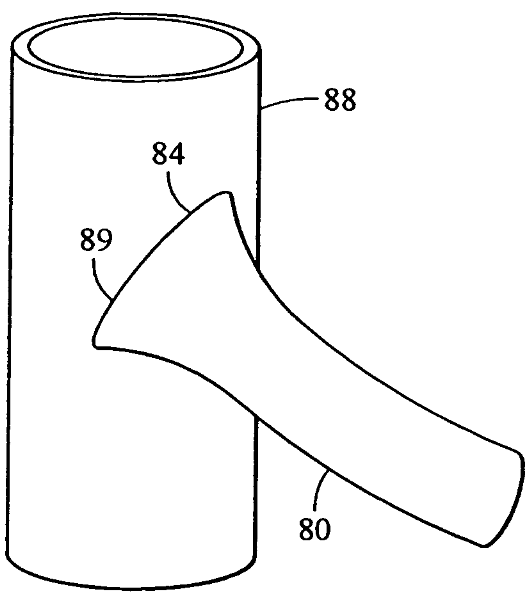

FIG. 5d

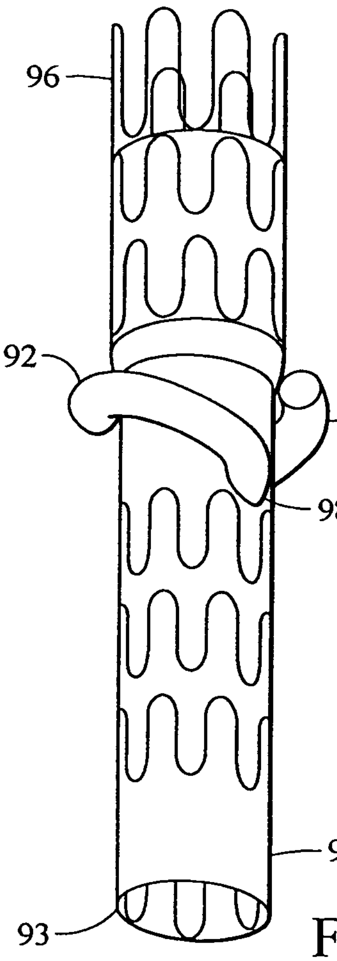

FIG. 6a

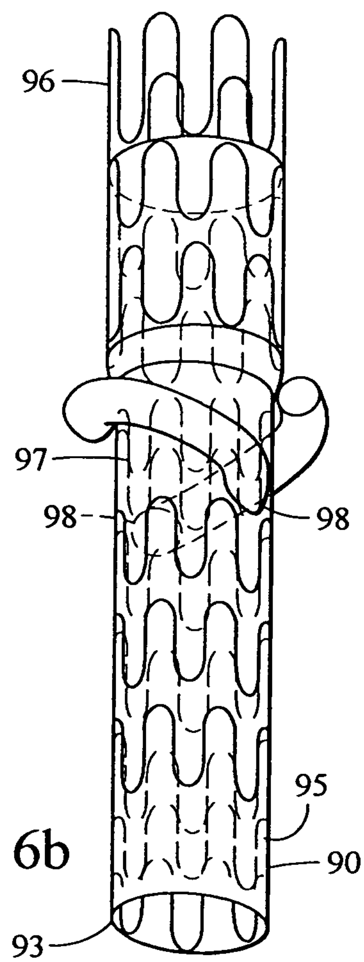

FIG. 6b

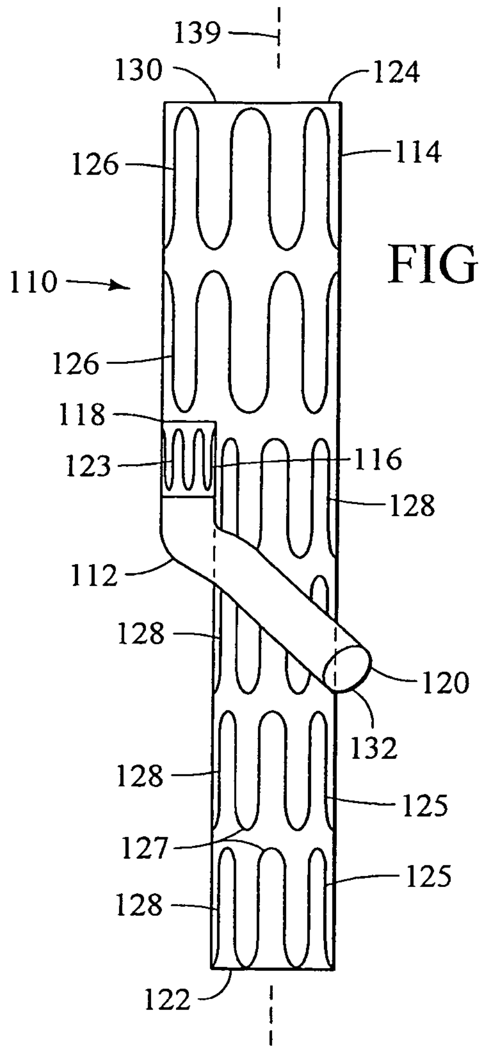
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FIG. 7a

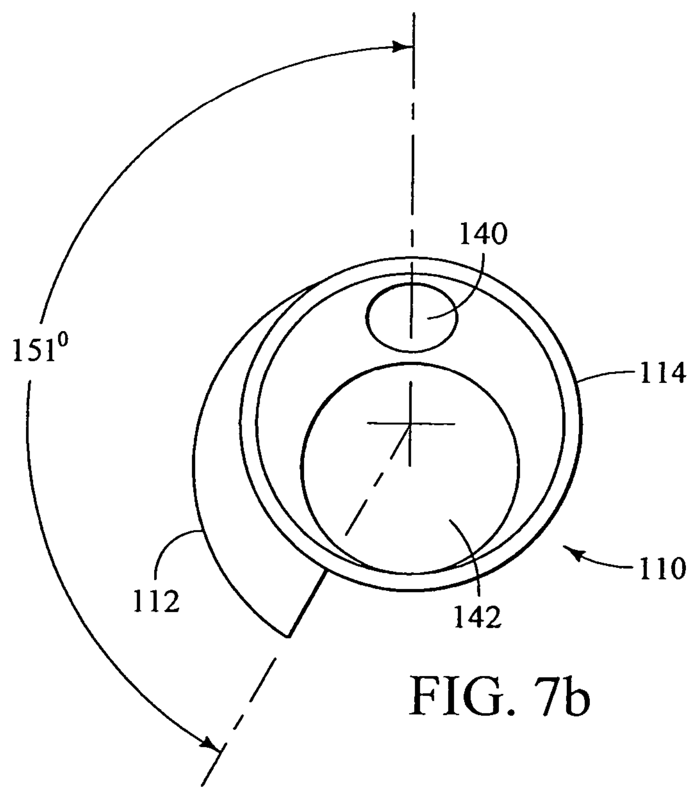
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FIG. 7b

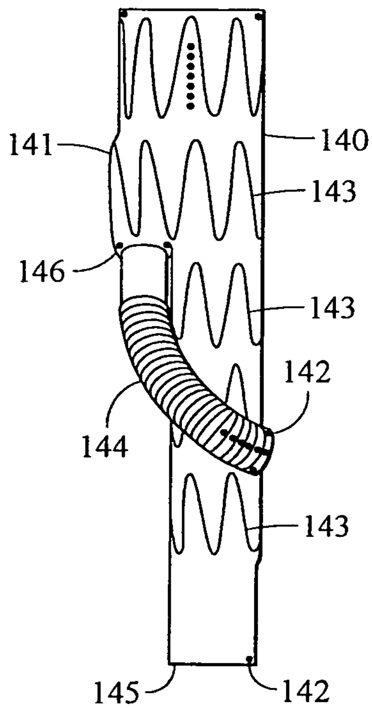
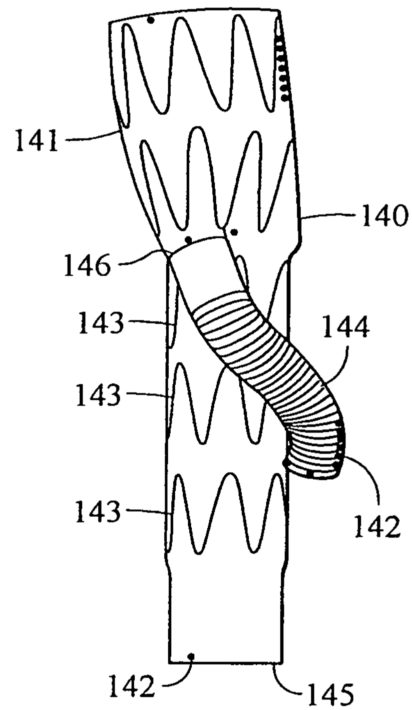


FIG. 8a



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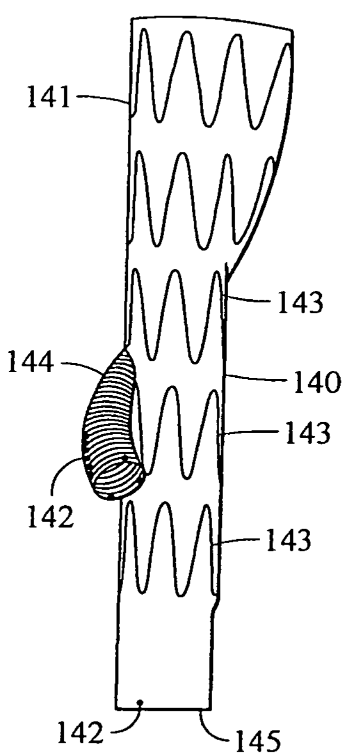

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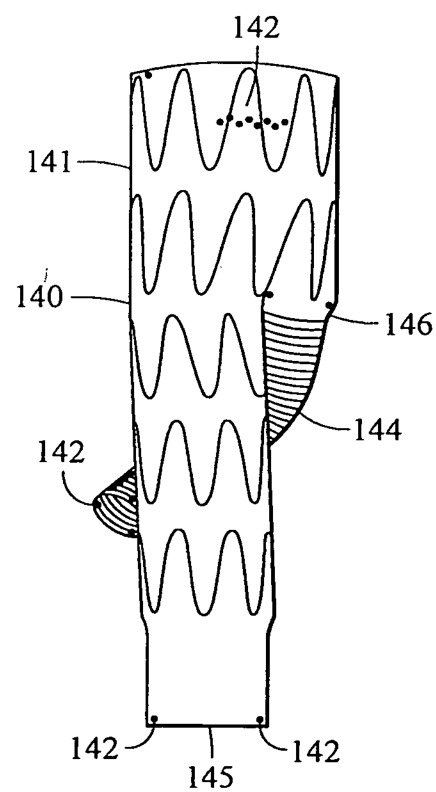

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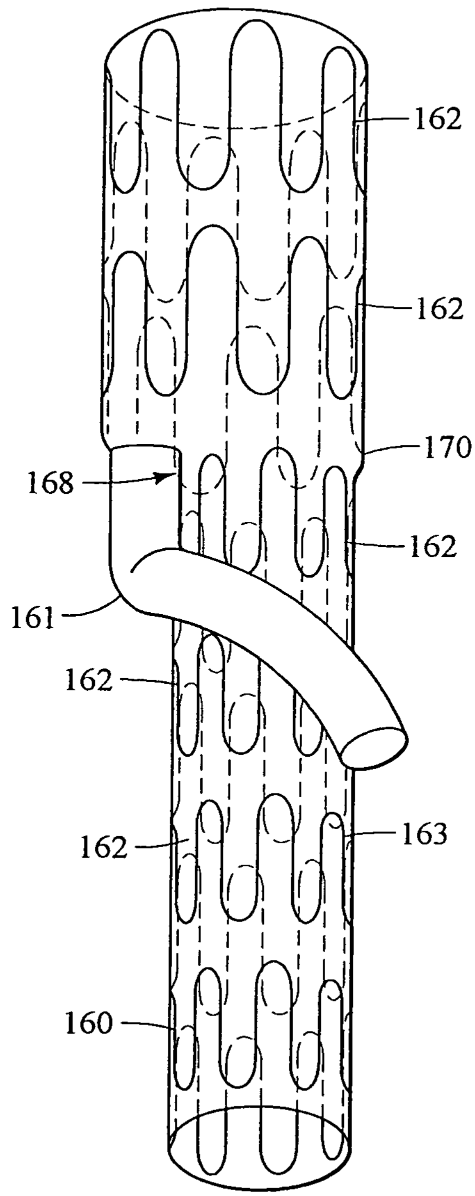
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FIG. 9a

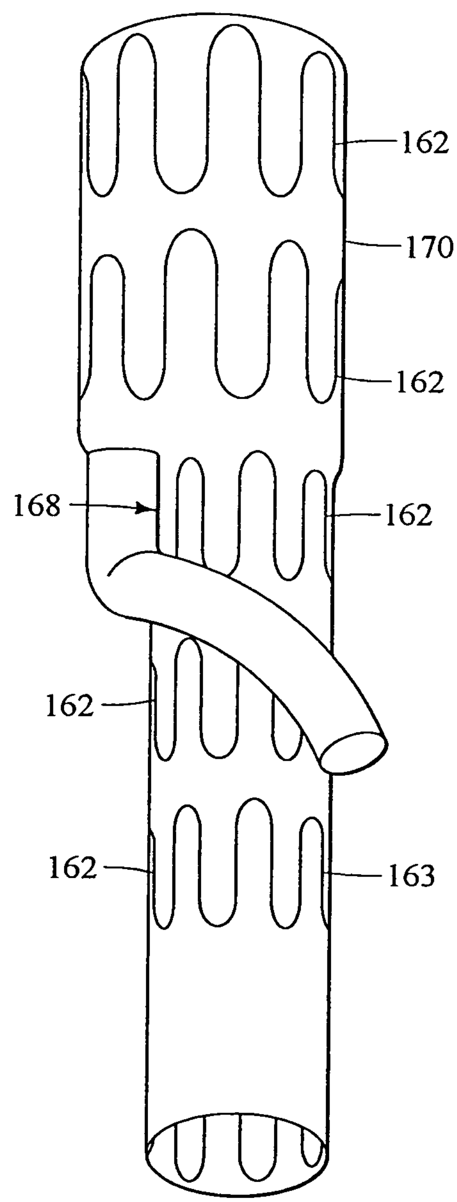
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FIG. 9b

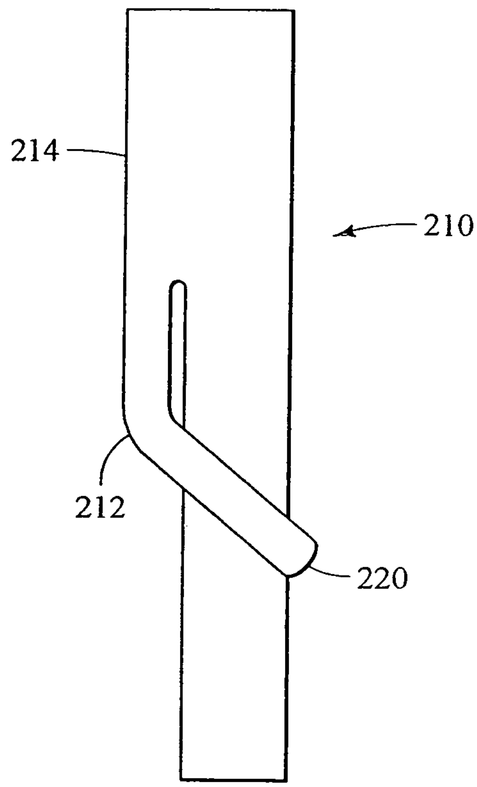


FIG. 10a

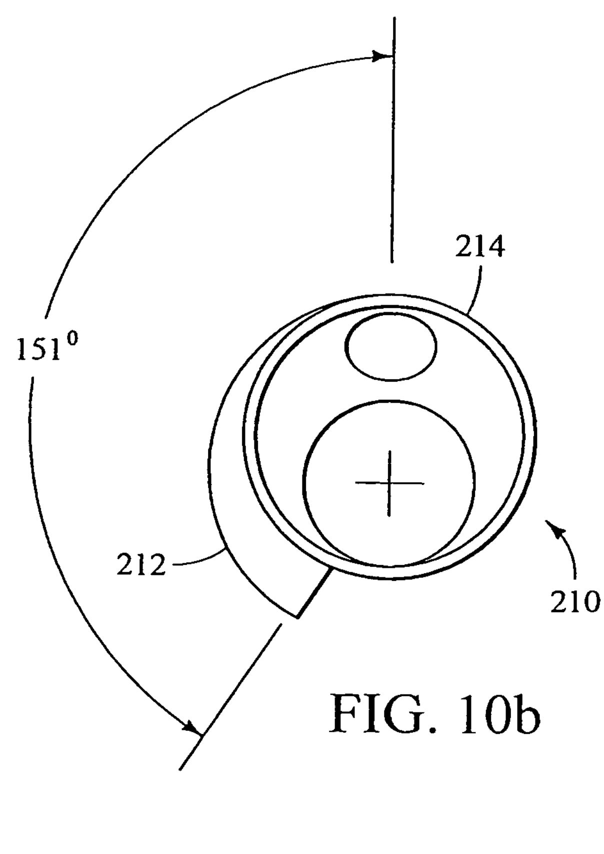


FIG. 10b

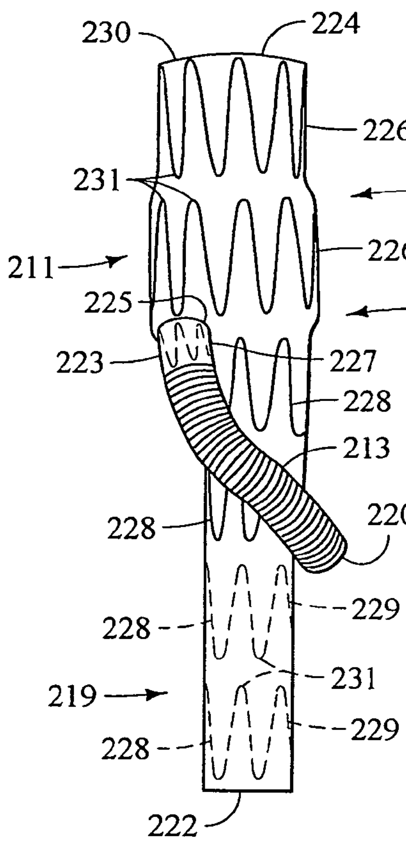
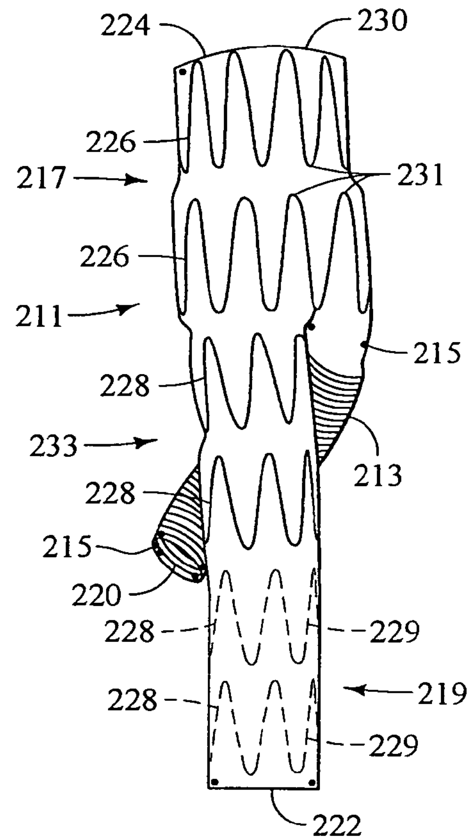


FIG. 11a



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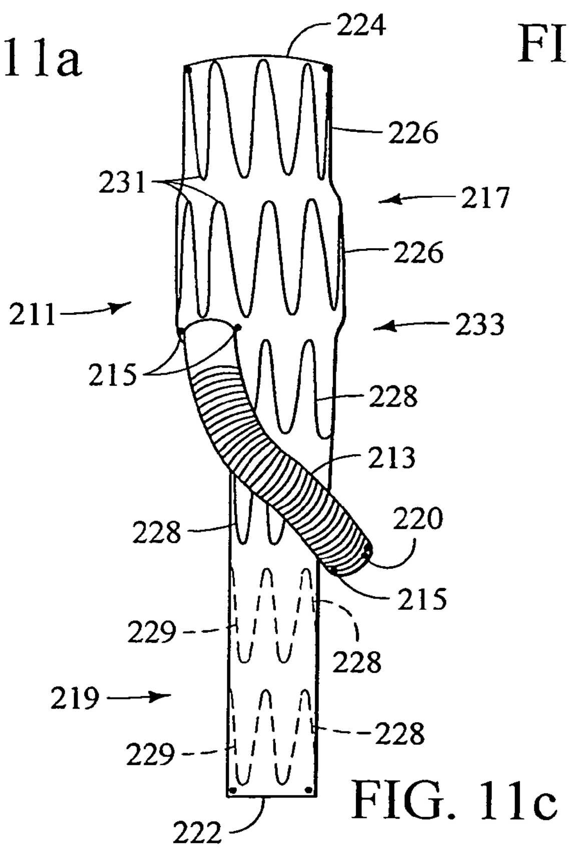

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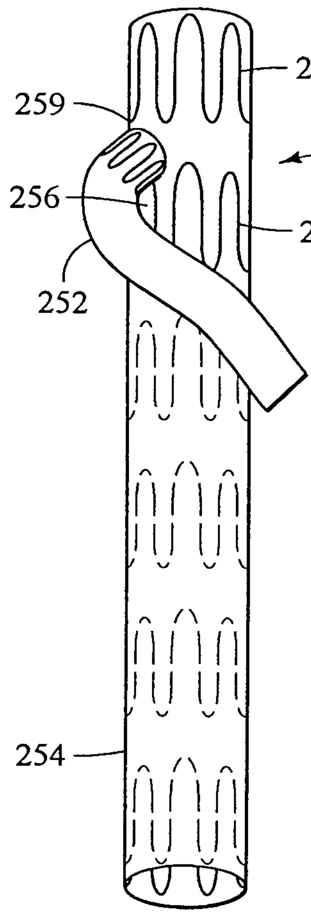


FIG. 12a

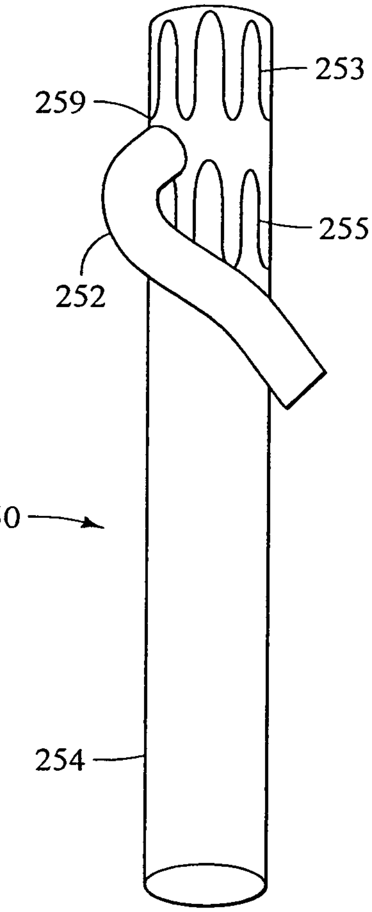
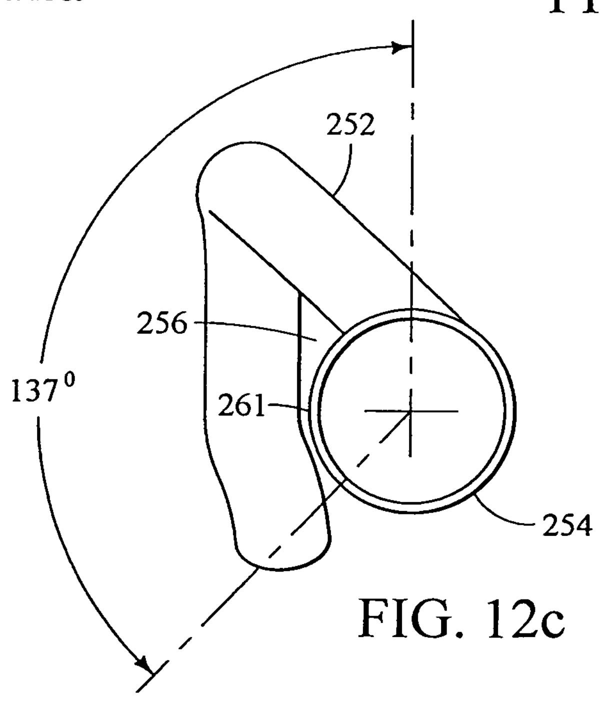


FIG. 12b



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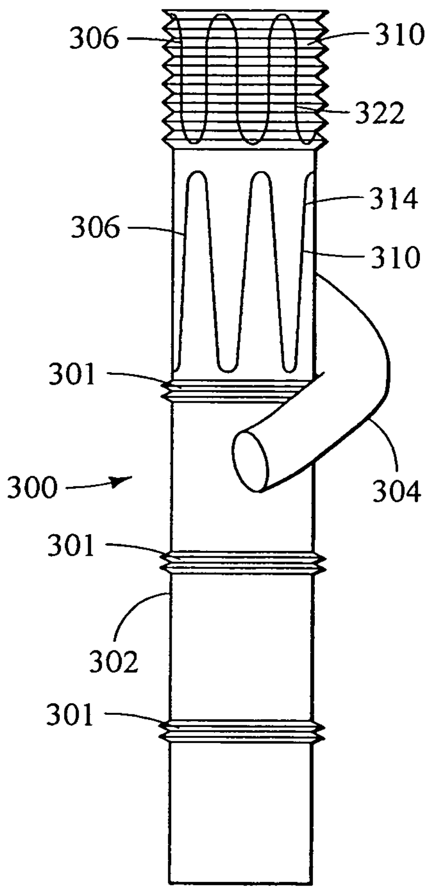


FIG. 13a

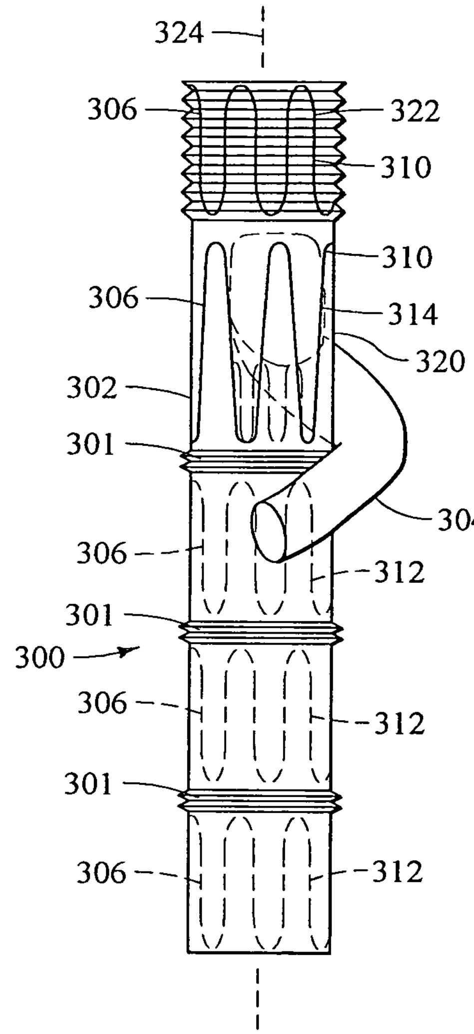
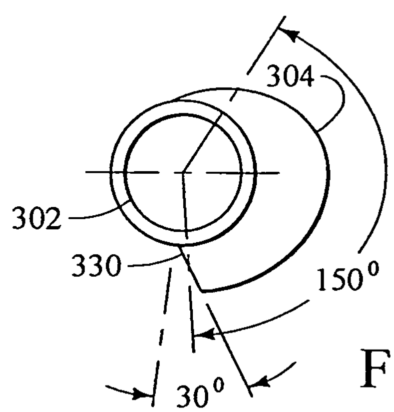


FIG. 13b



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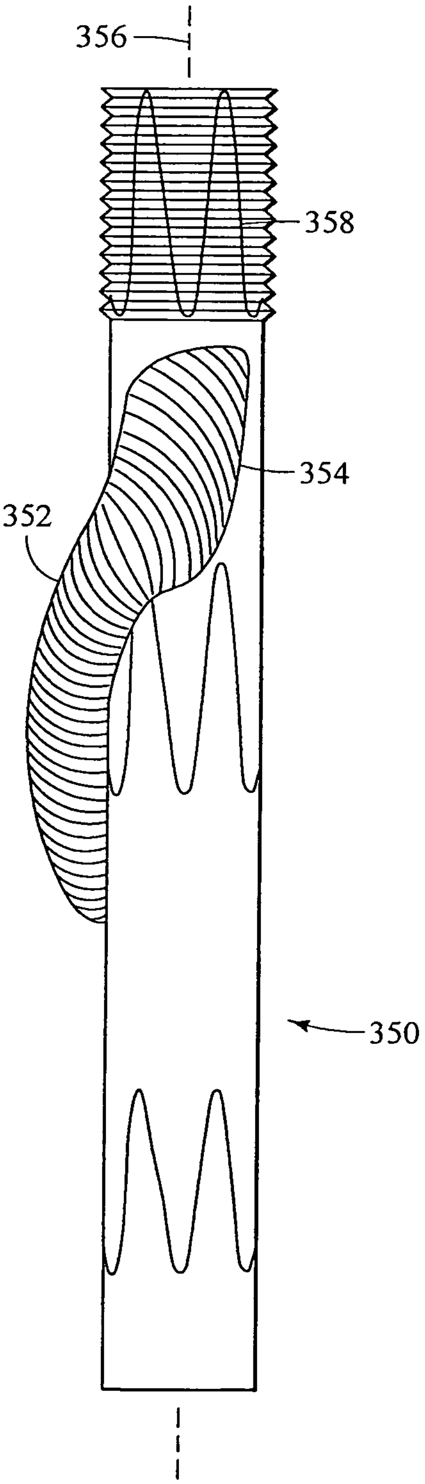

FIG. 14a

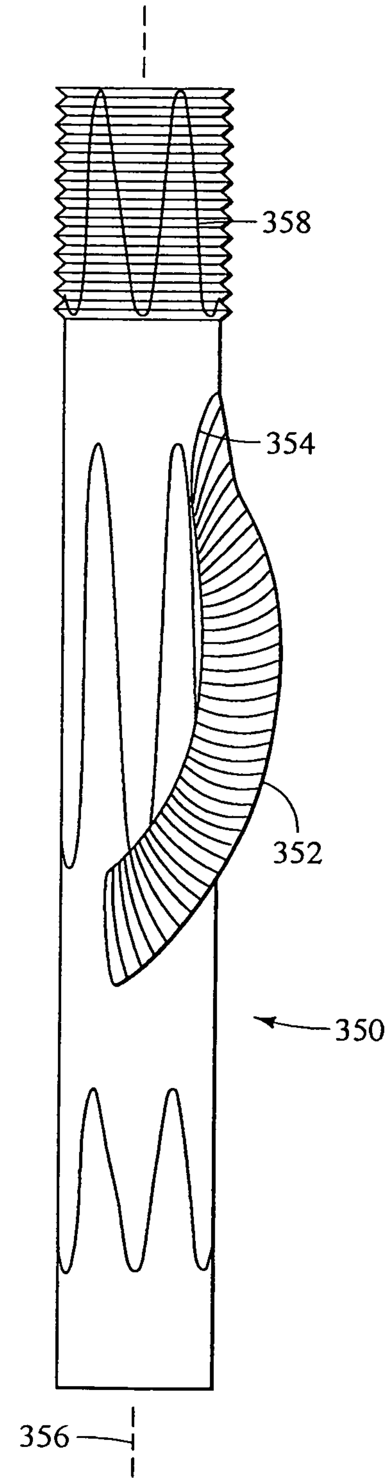

FIG. 14b

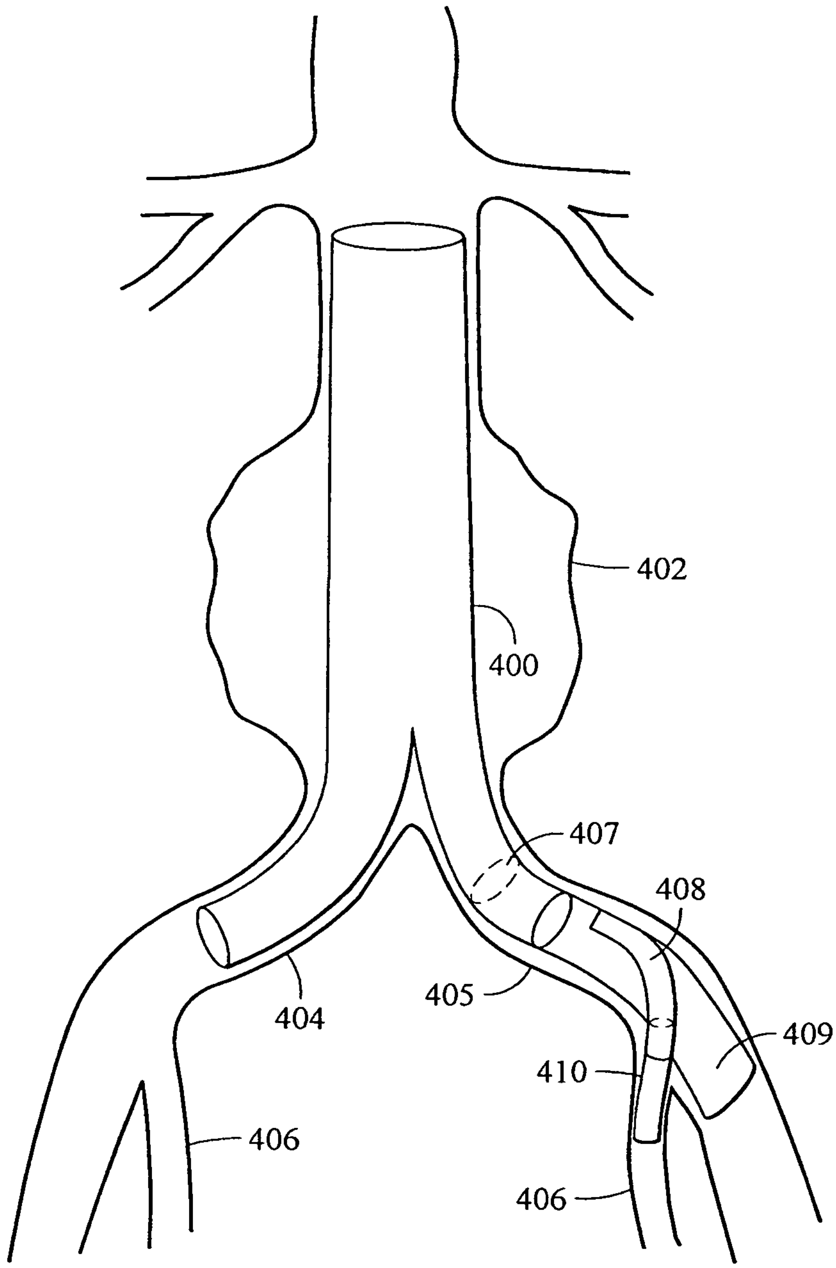

FIG. 15a

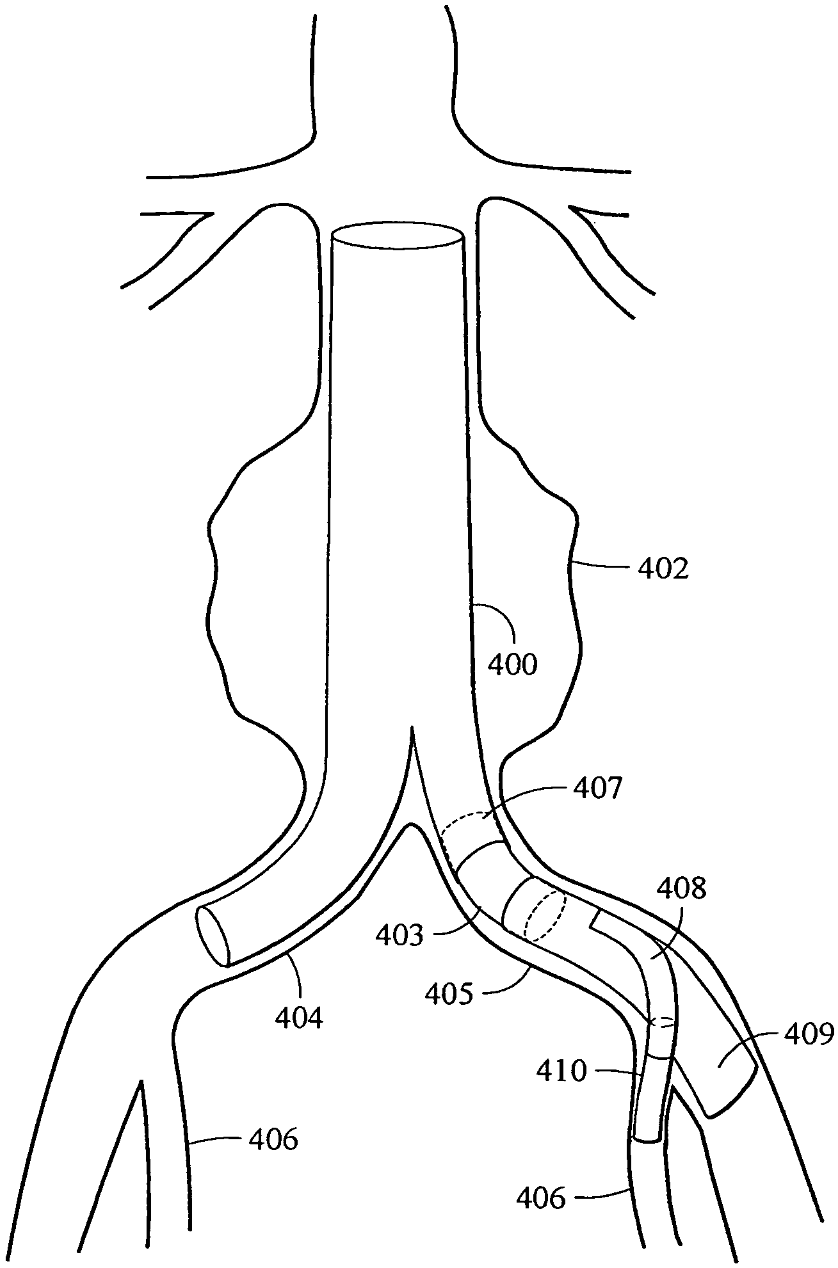

FIG. 15b

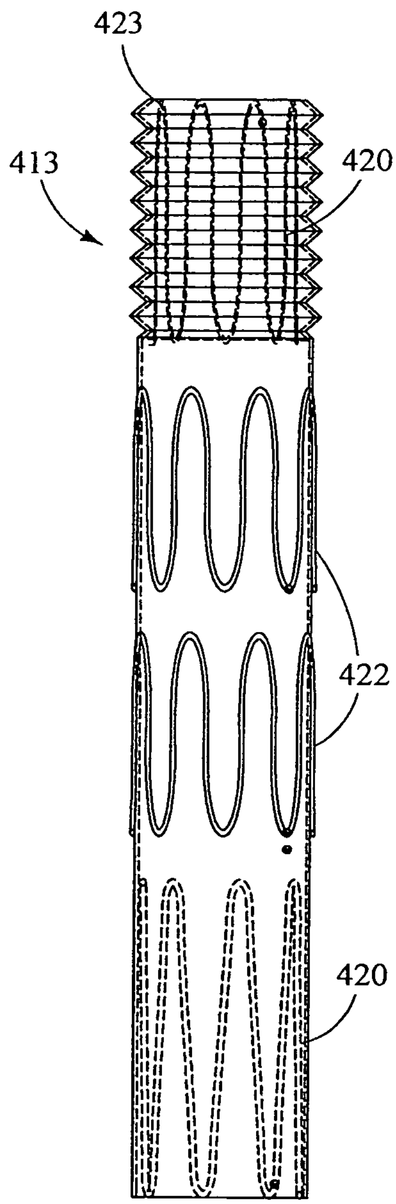

FIG. 15c

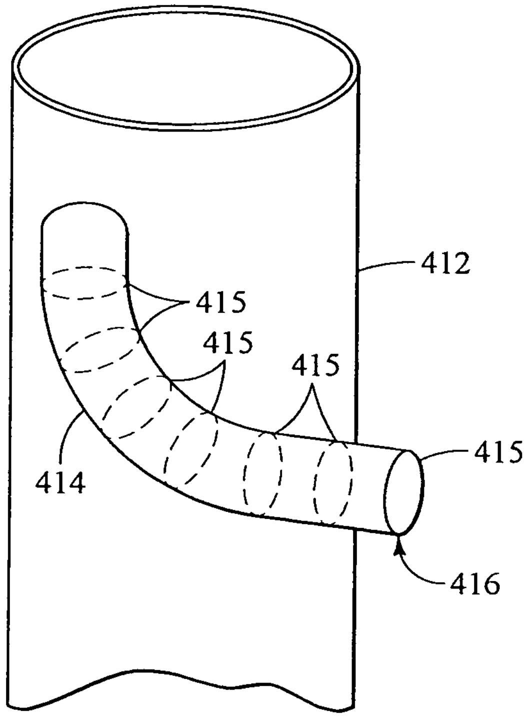

FIG. 16

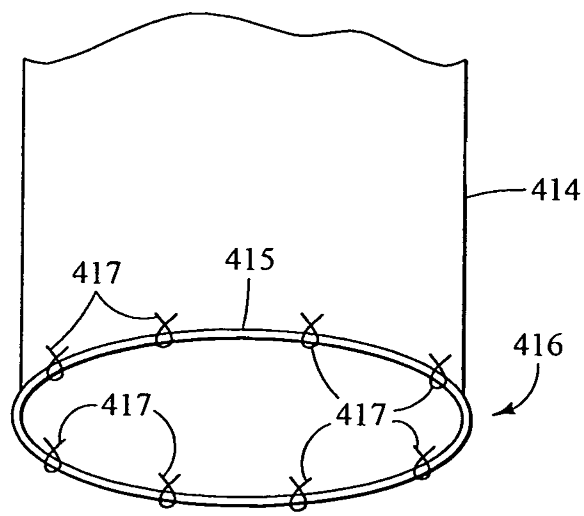

FIG. 17

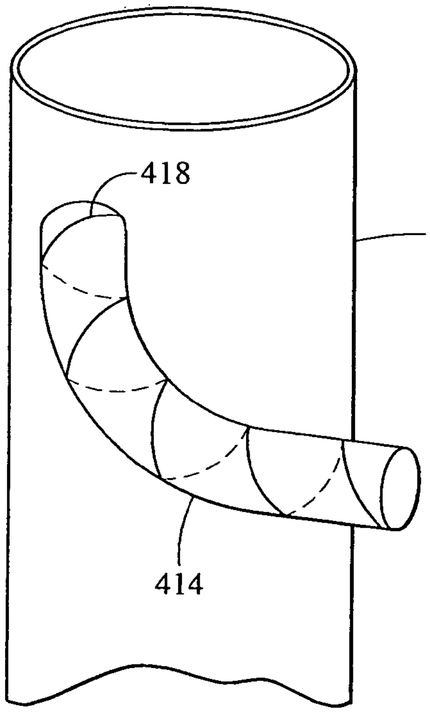

FIG. 18

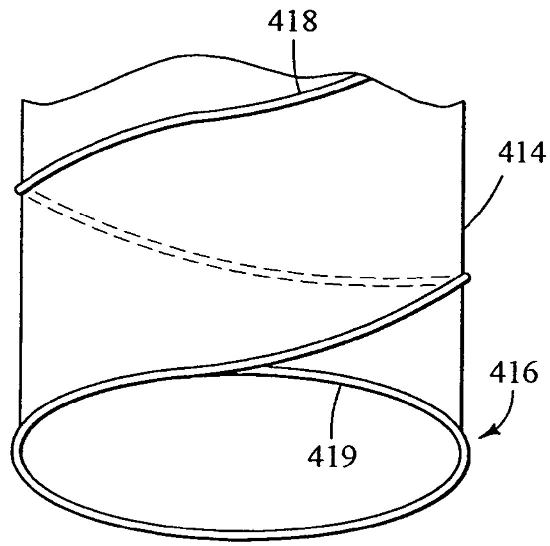

FIG. 19

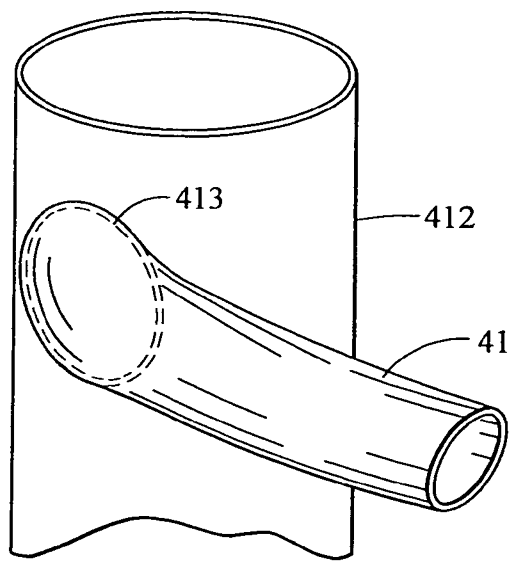

FIG. 20

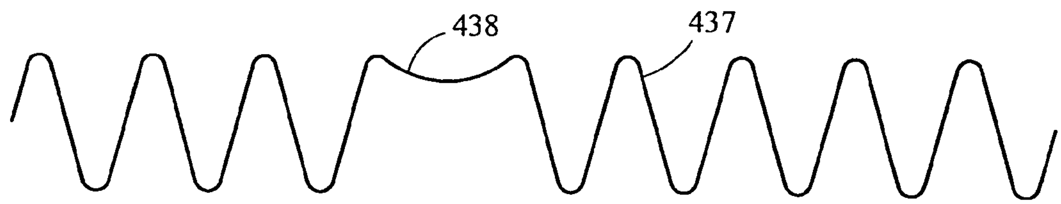

FIG. 21a

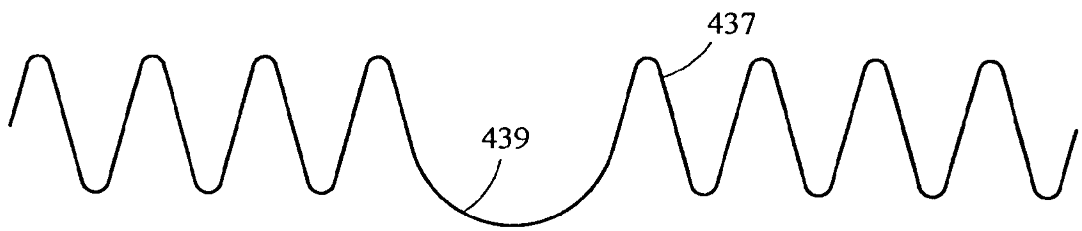

FIG. 21b

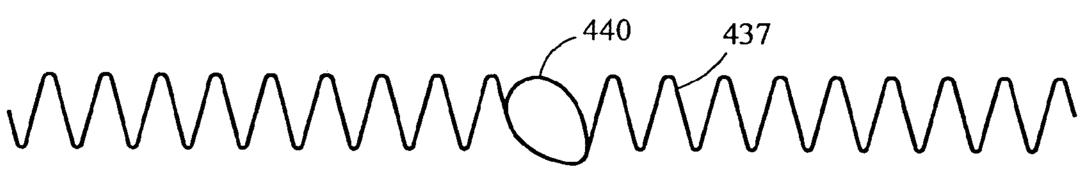

FIG. 21c

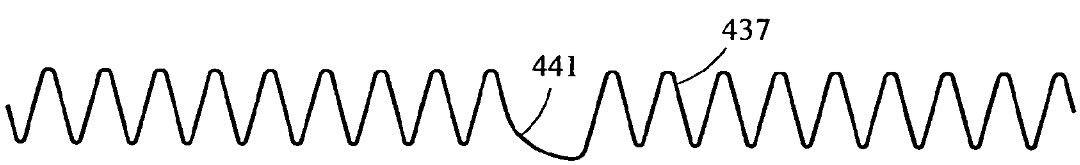

FIG. 21d

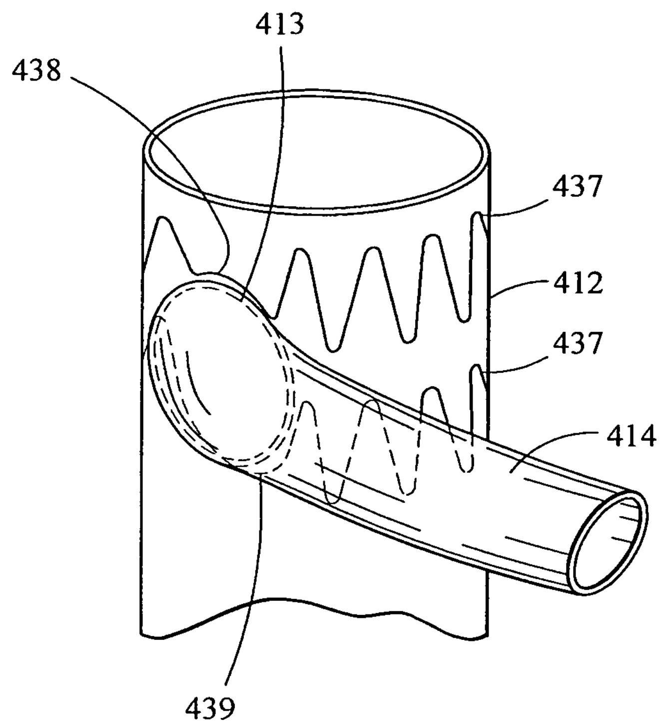

FIG. 22a

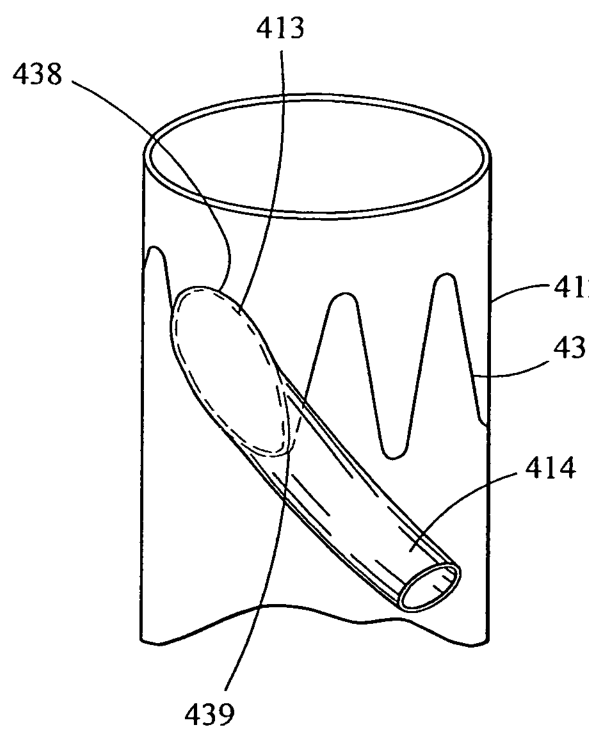

FIG. 22b

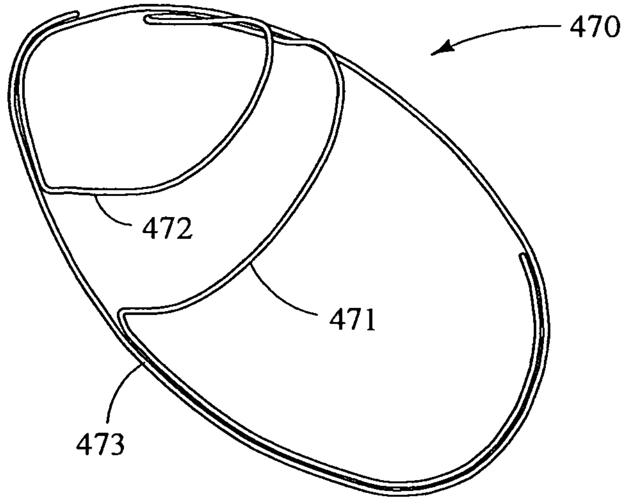

FIG. 23a

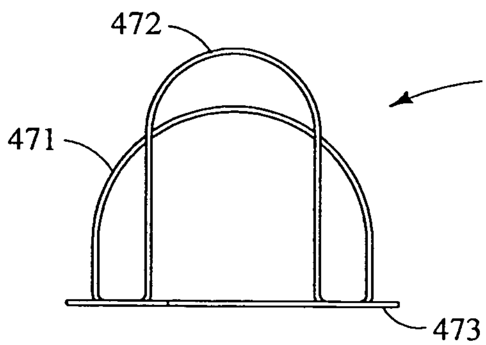

FIG. 23b

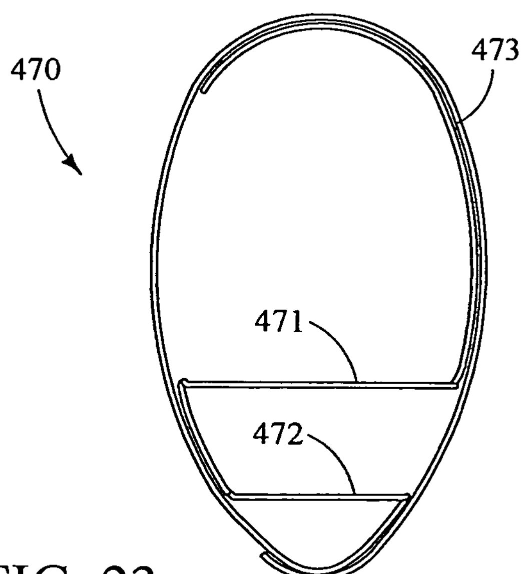

FIG. 23c

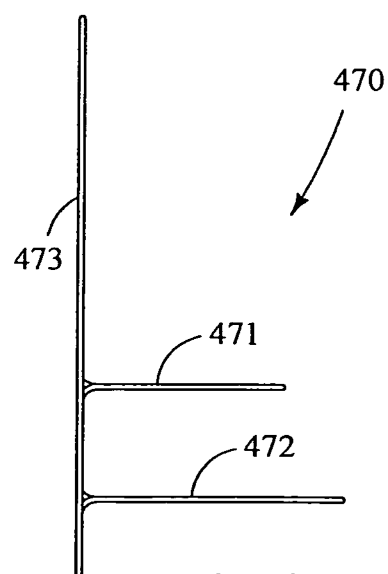

FIG. 23d

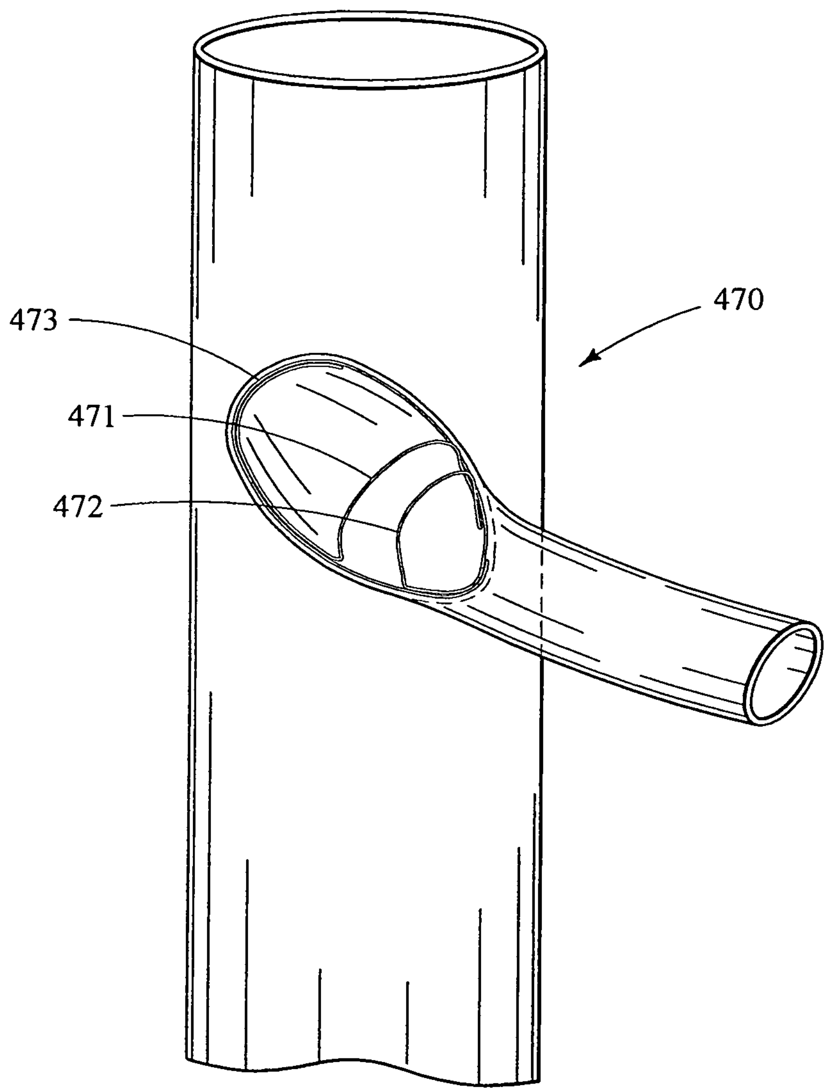

FIG. 23e

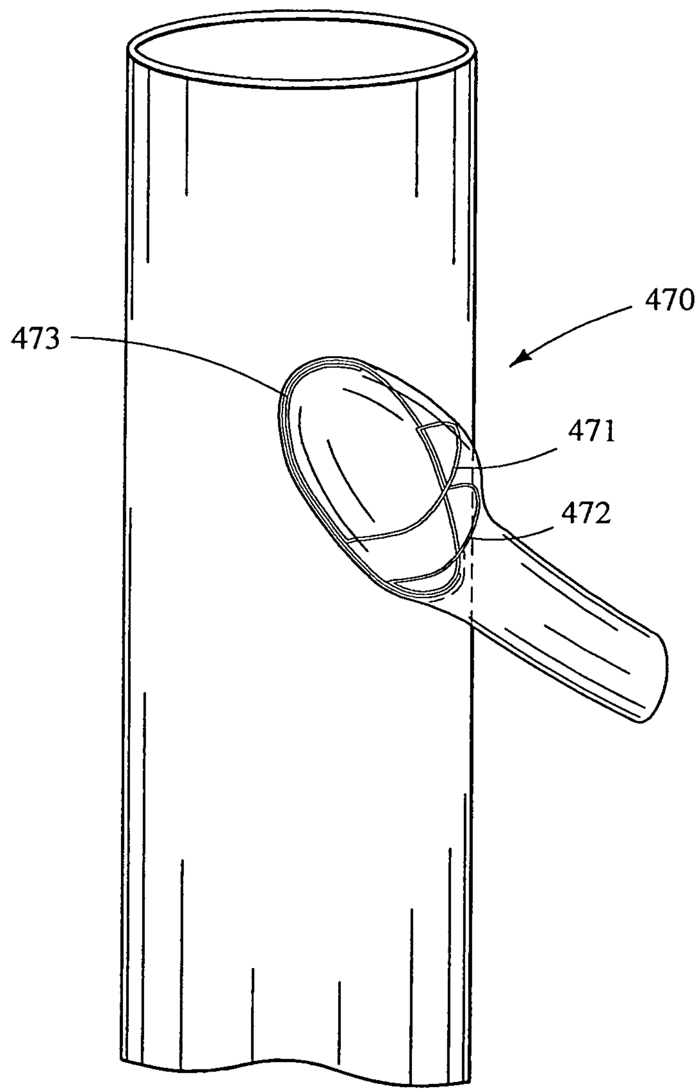

FIG. 23f

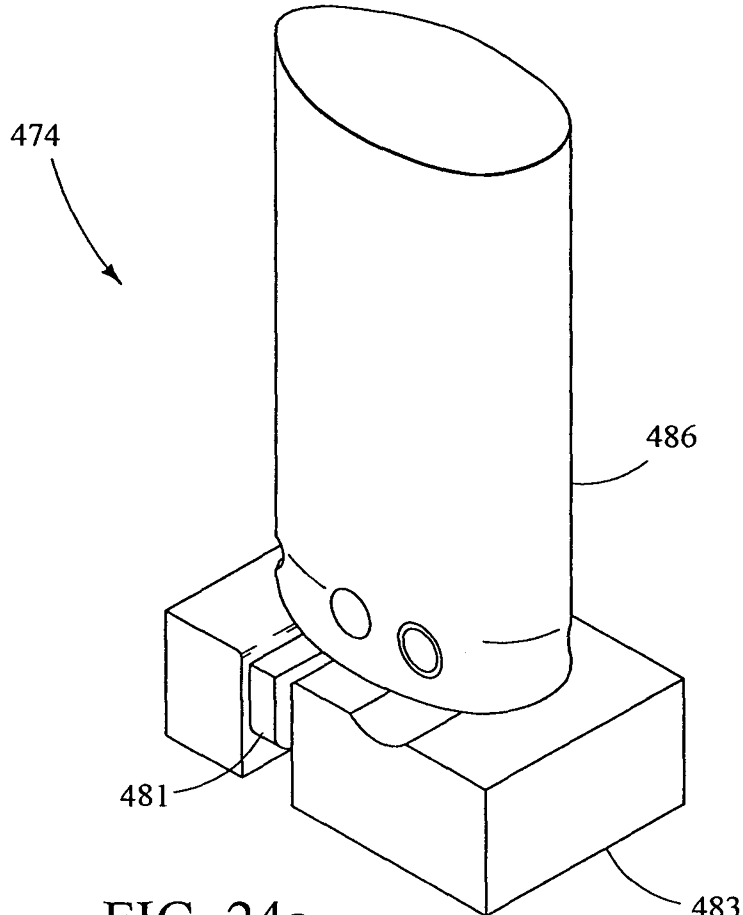

FIG. 24a

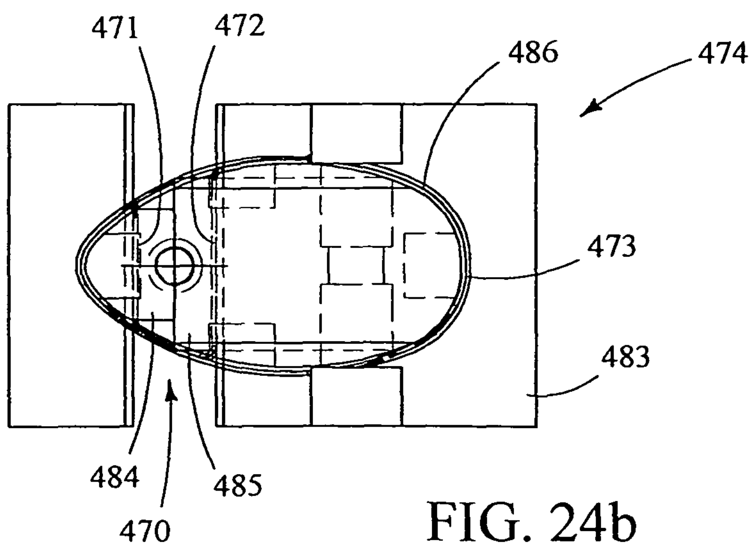

FIG. 24b

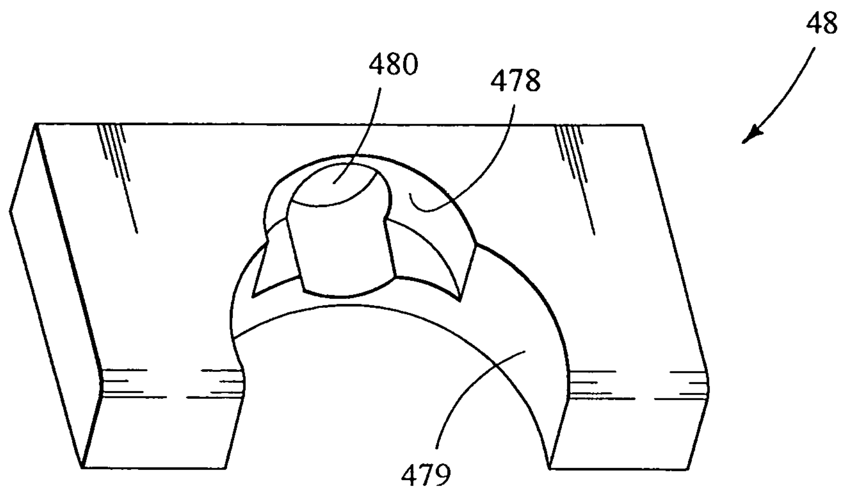

FIG. 24c

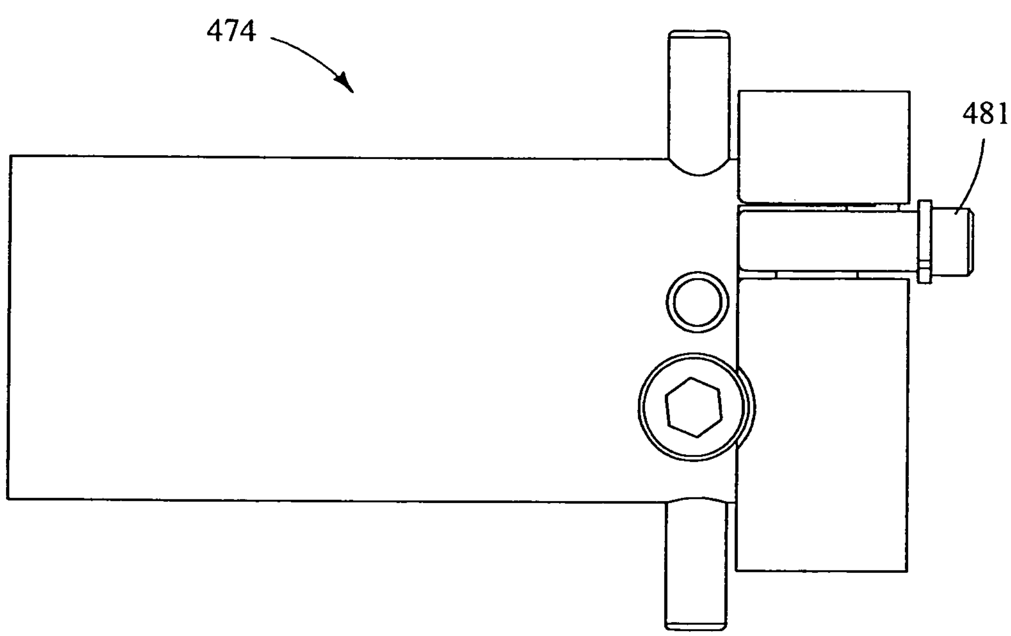

FIG. 24d

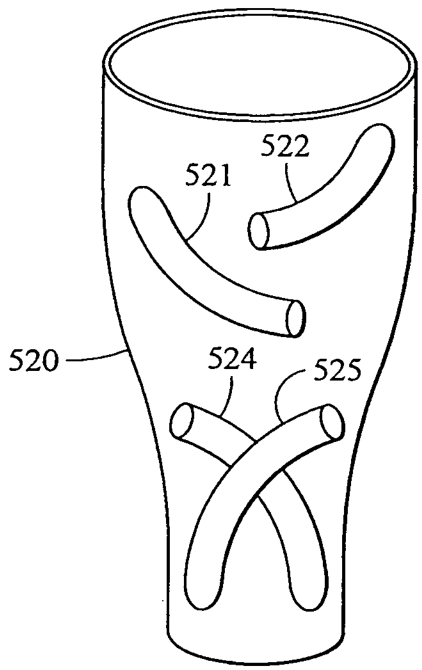

FIG. 25

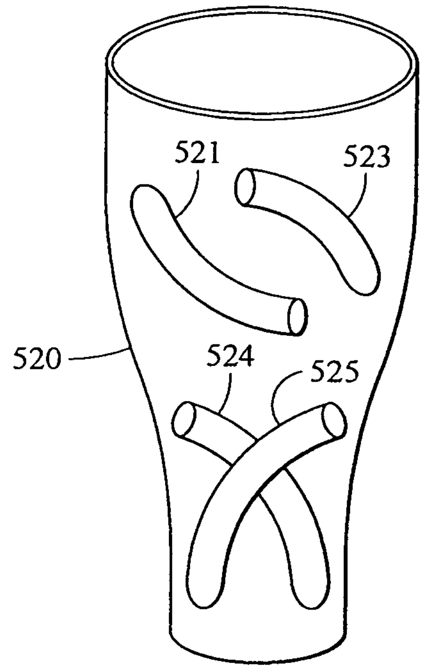

FIG. 26

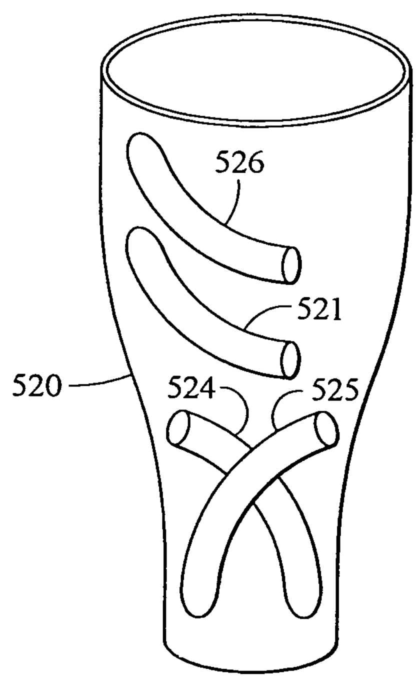

FIG. 27a

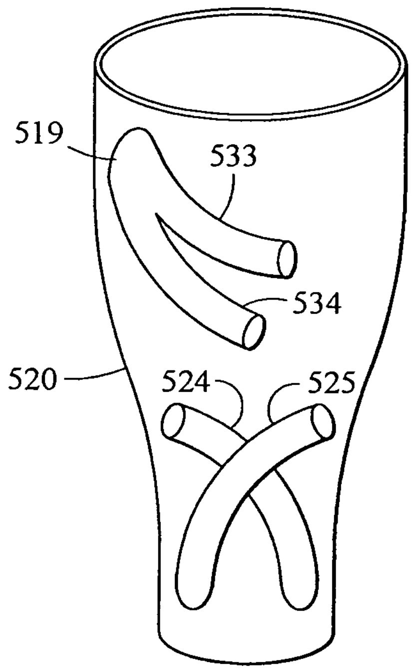

FIG. 27b

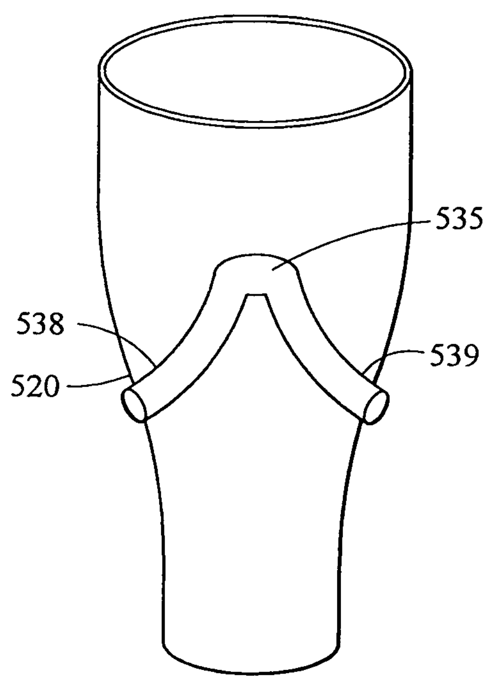

FIG. 27c

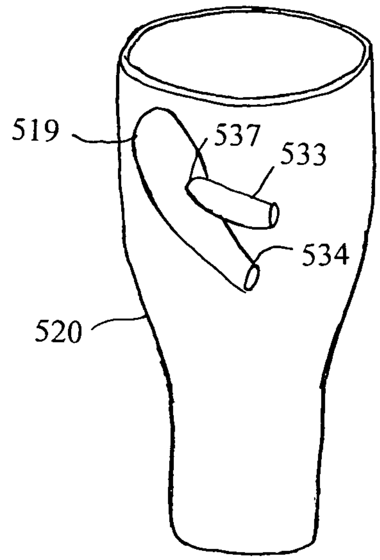

FIG. 27d

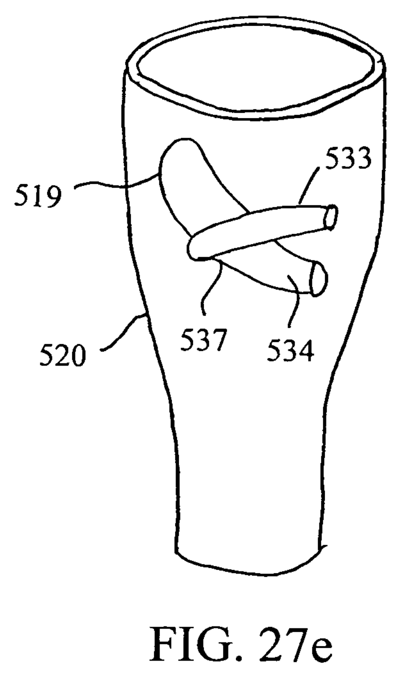

FIG. 27e

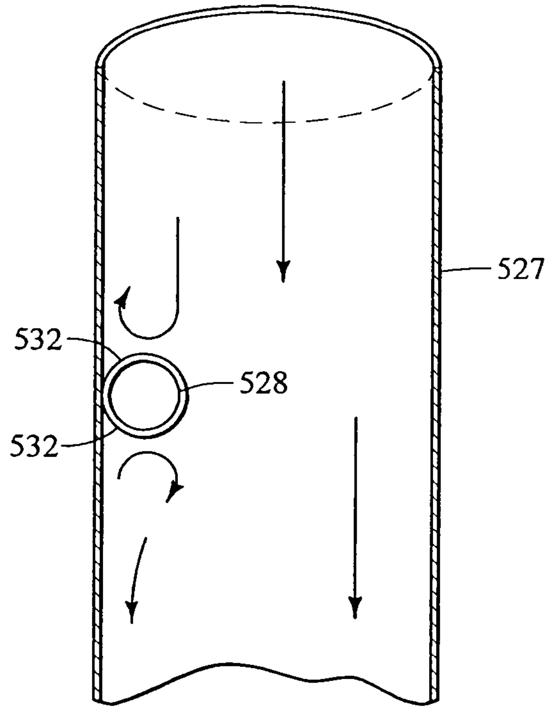

FIG. 28b

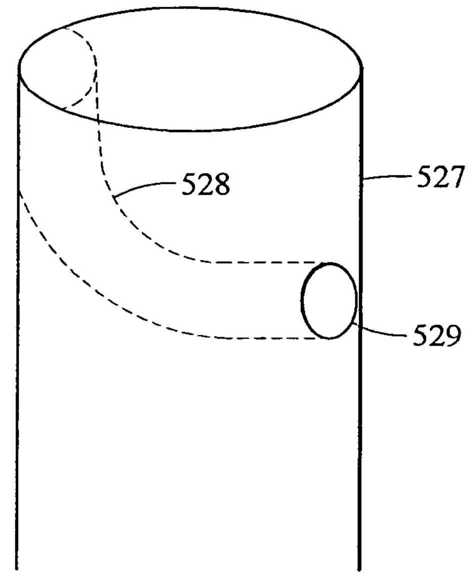

FIG. 28a

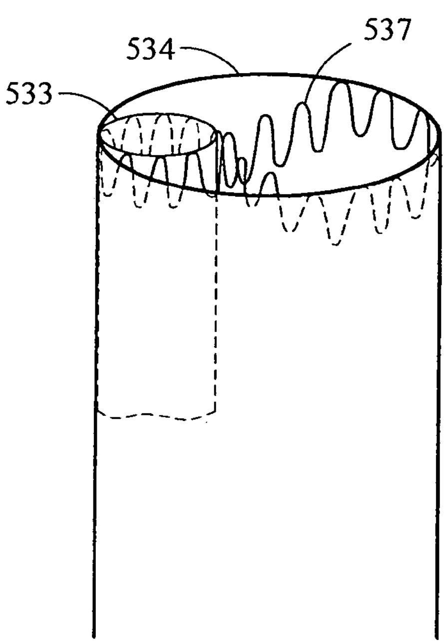

FIG. 28c

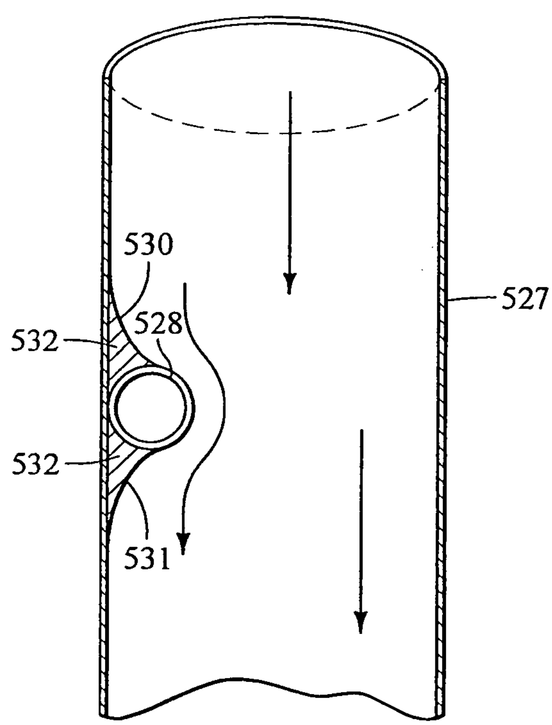

FIG. 29

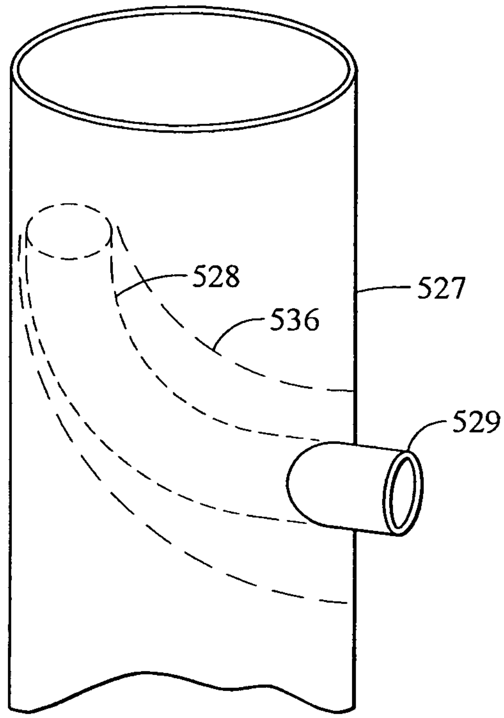

FIG. 30

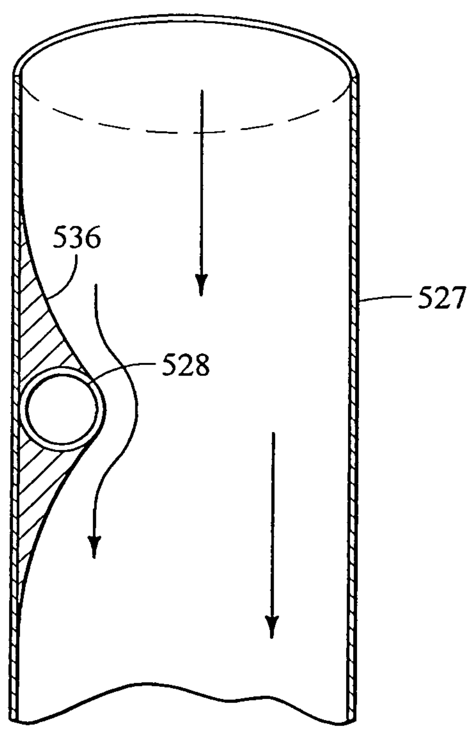

FIG. 31

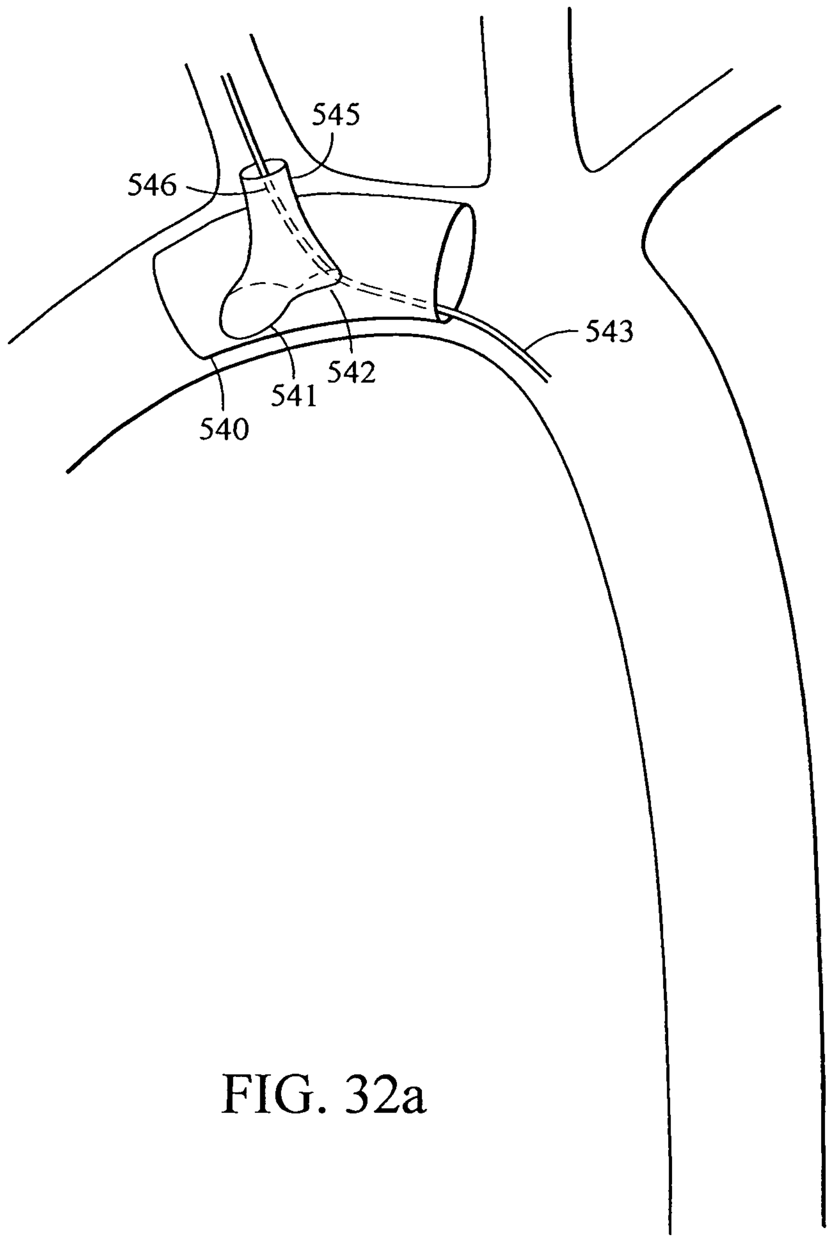

FIG. 32a

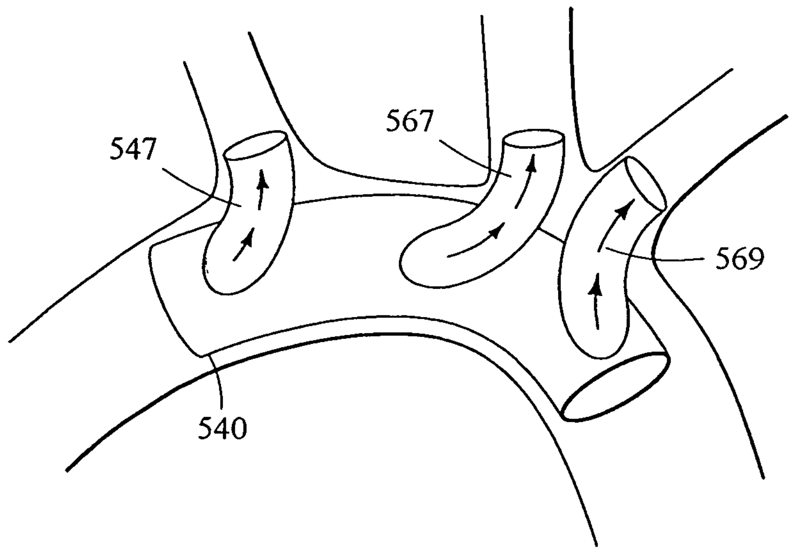

FIG. 32b

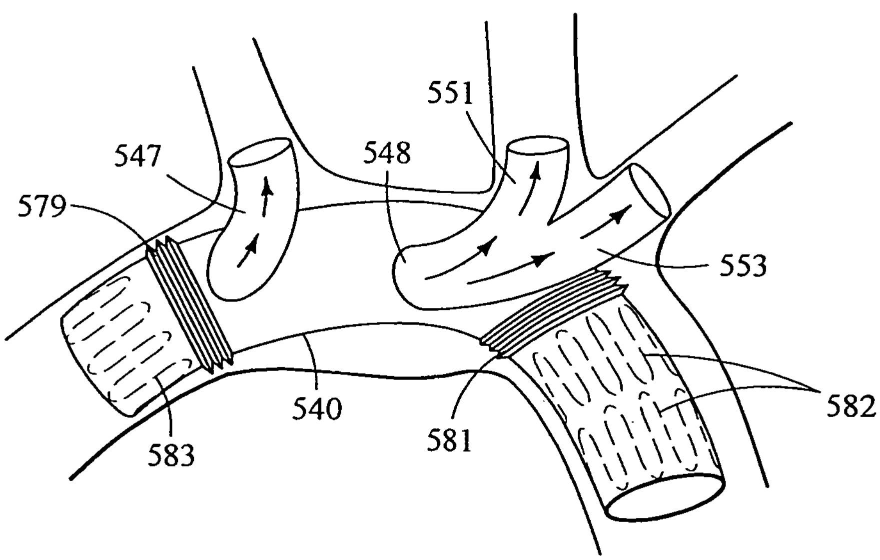

FIG. 32c

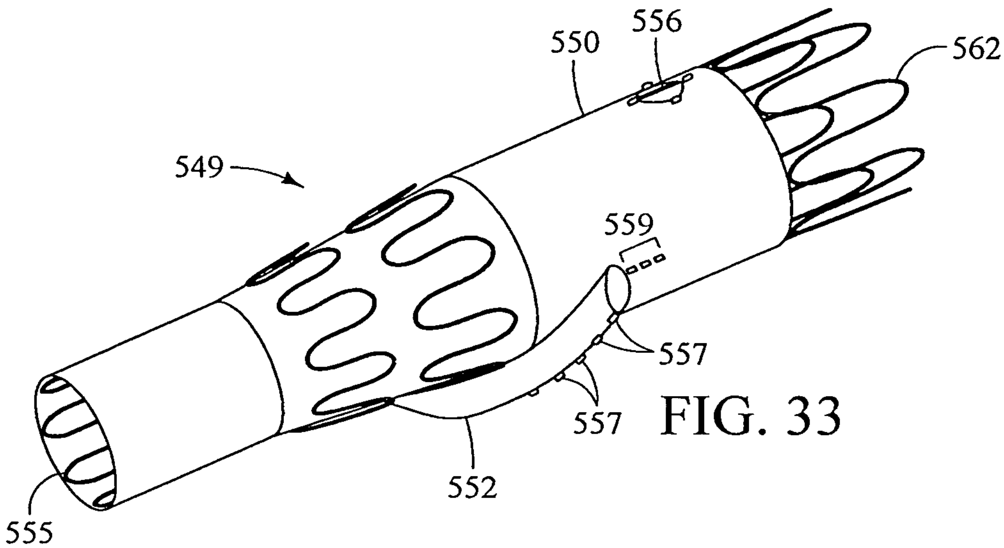

FIG. 33

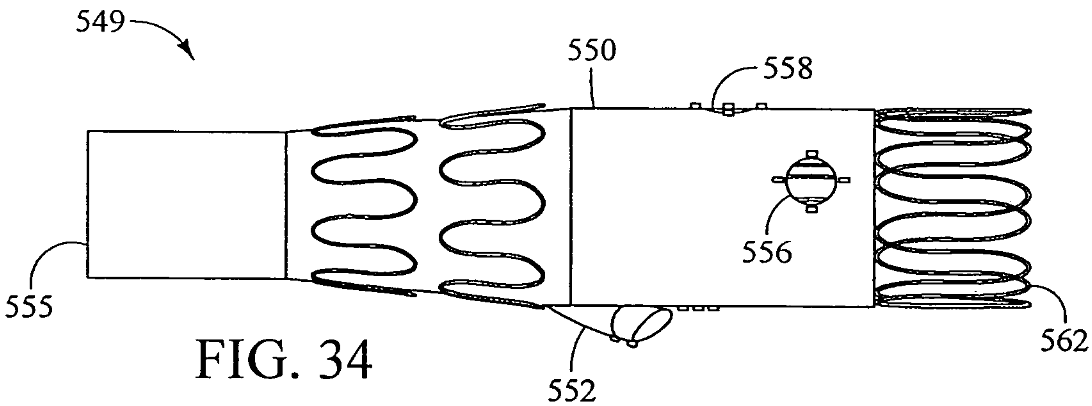

FIG. 34

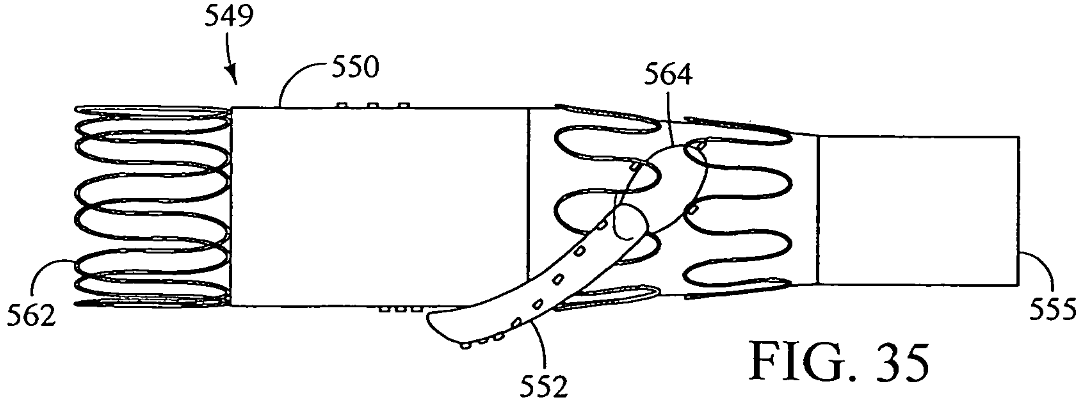

FIG. 35

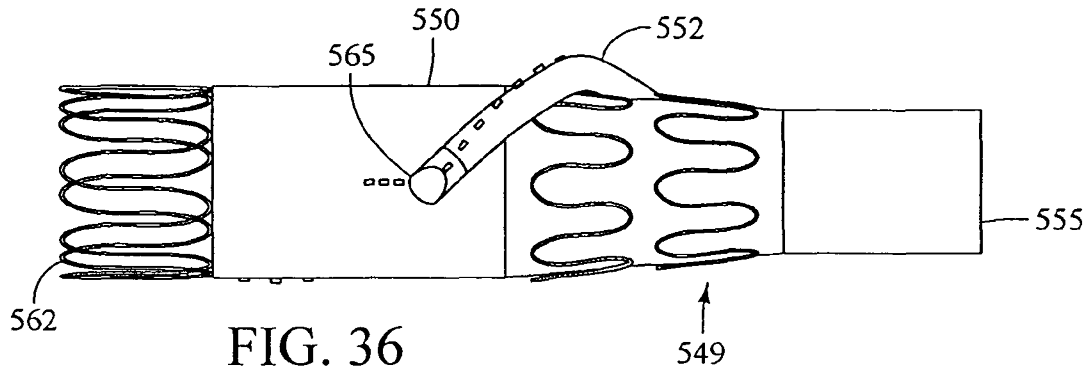

FIG. 36

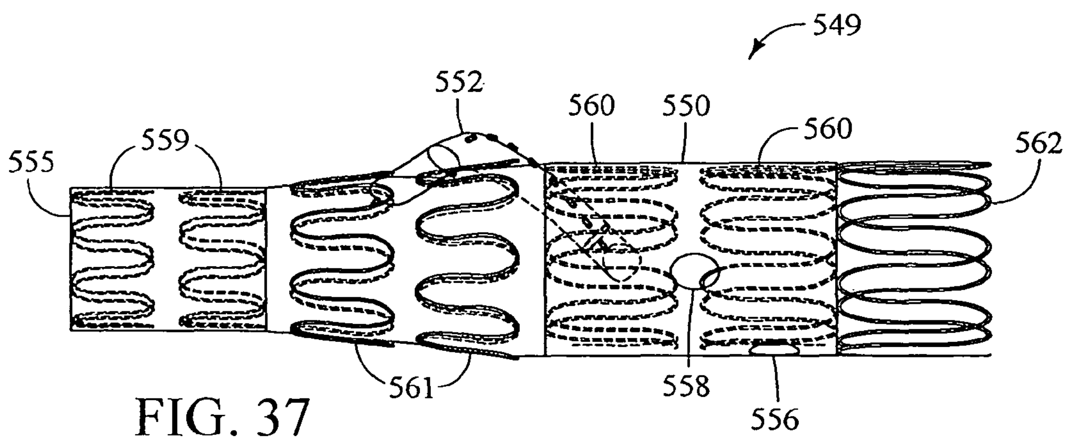

FIG. 37

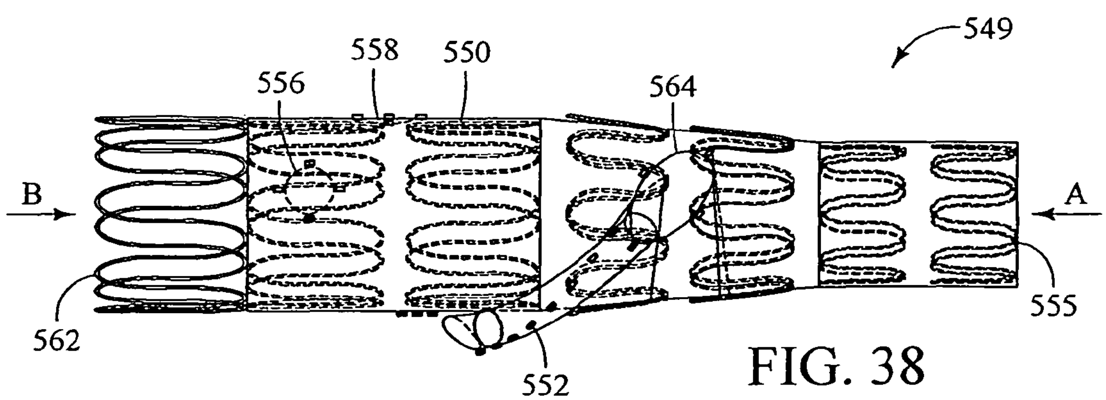

FIG. 38

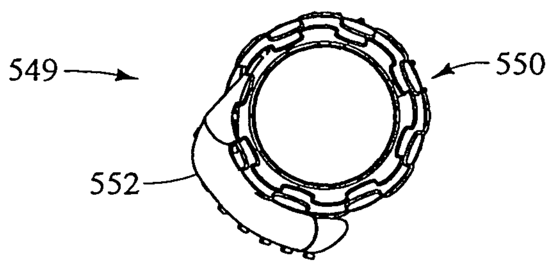

FIG. 39

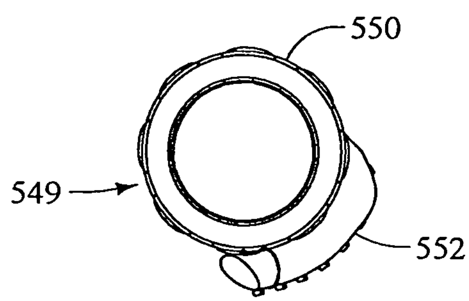

FIG. 40

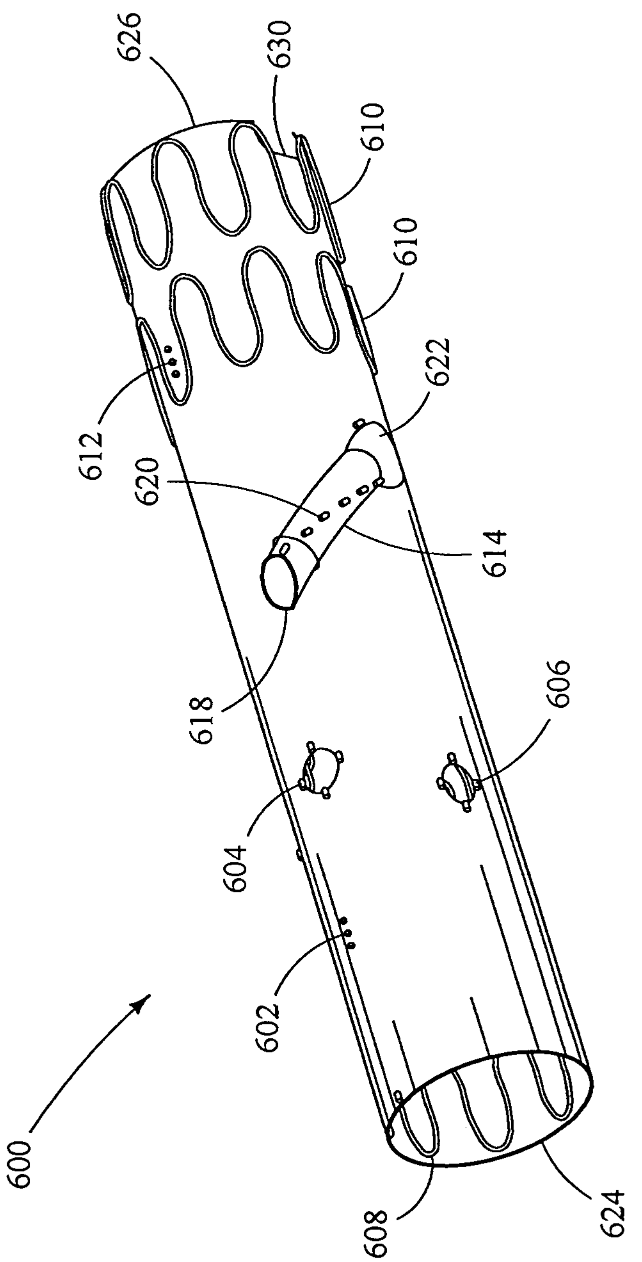

FIG. 41a

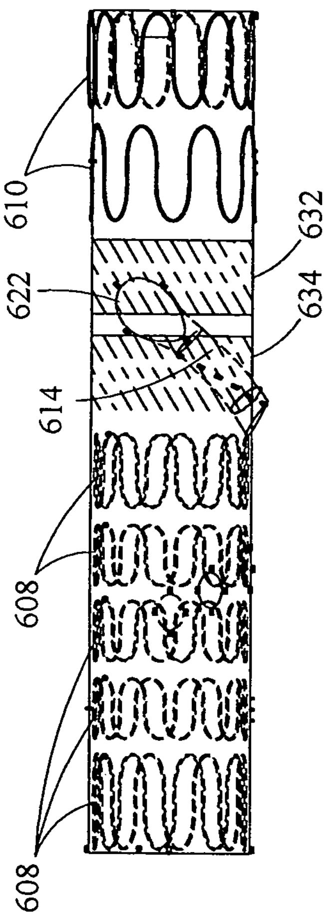

FIG. 41c

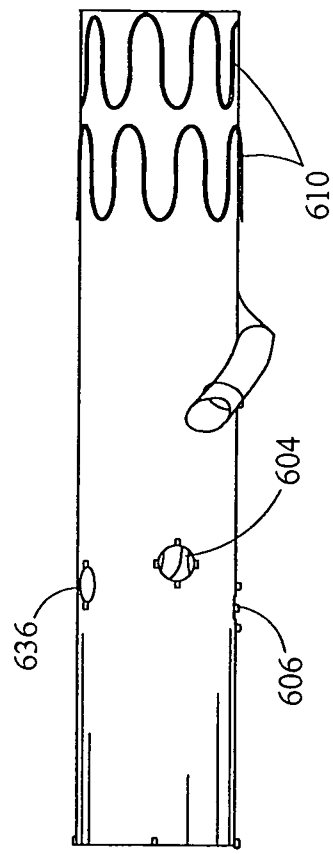

FIG. 41b

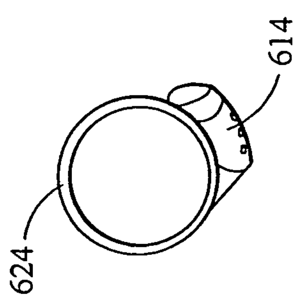

FIG. 41d

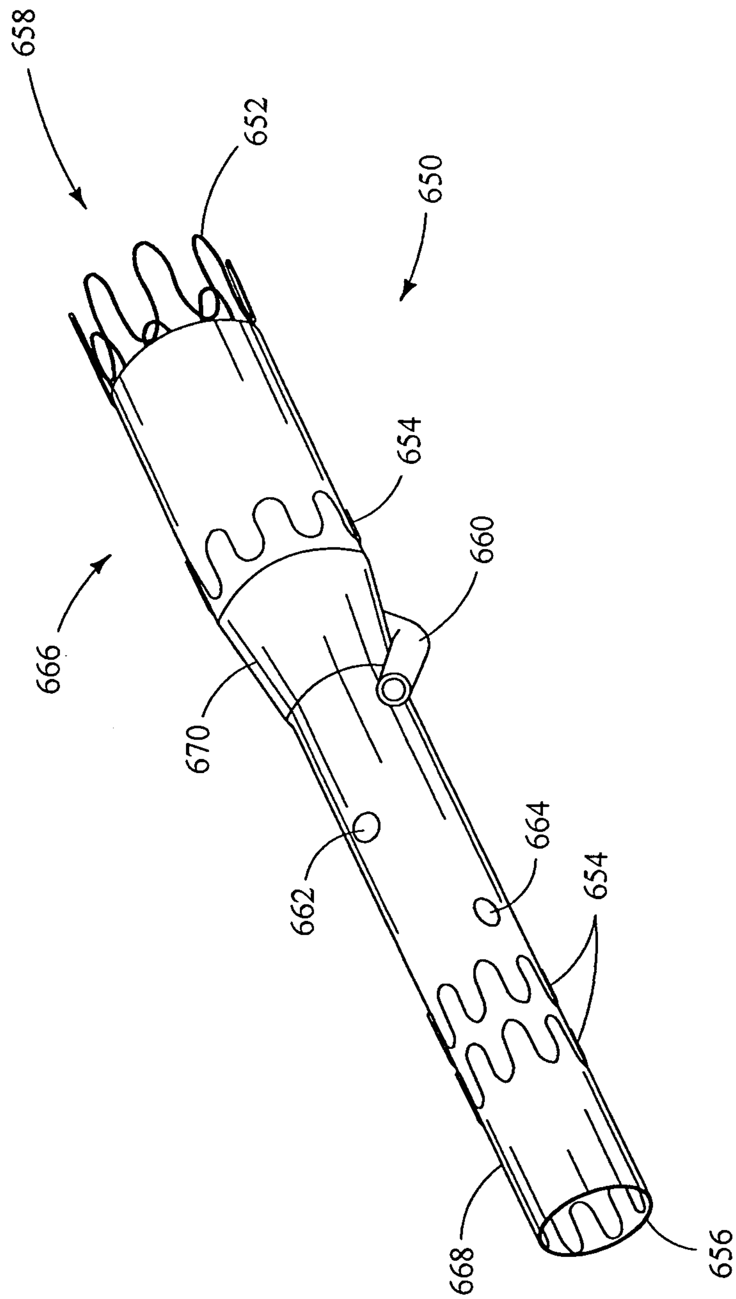

FIG. 42a

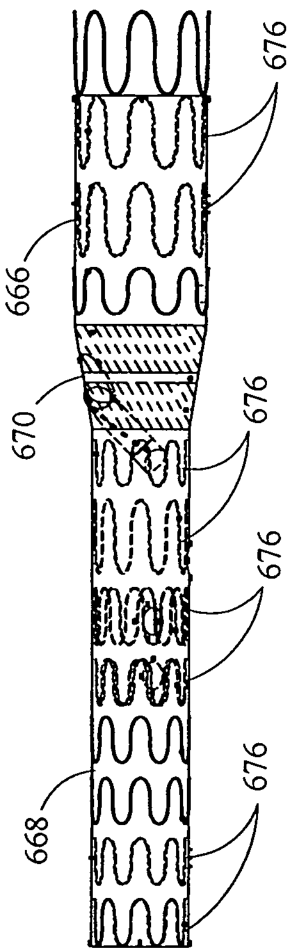

FIG. 42b

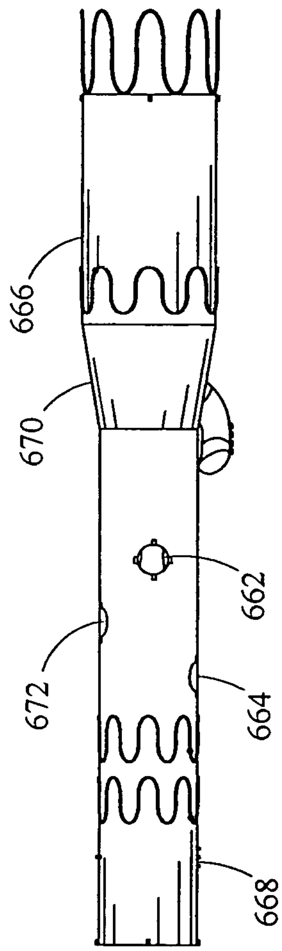

FIG. 42c

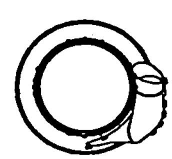

FIG. 42d

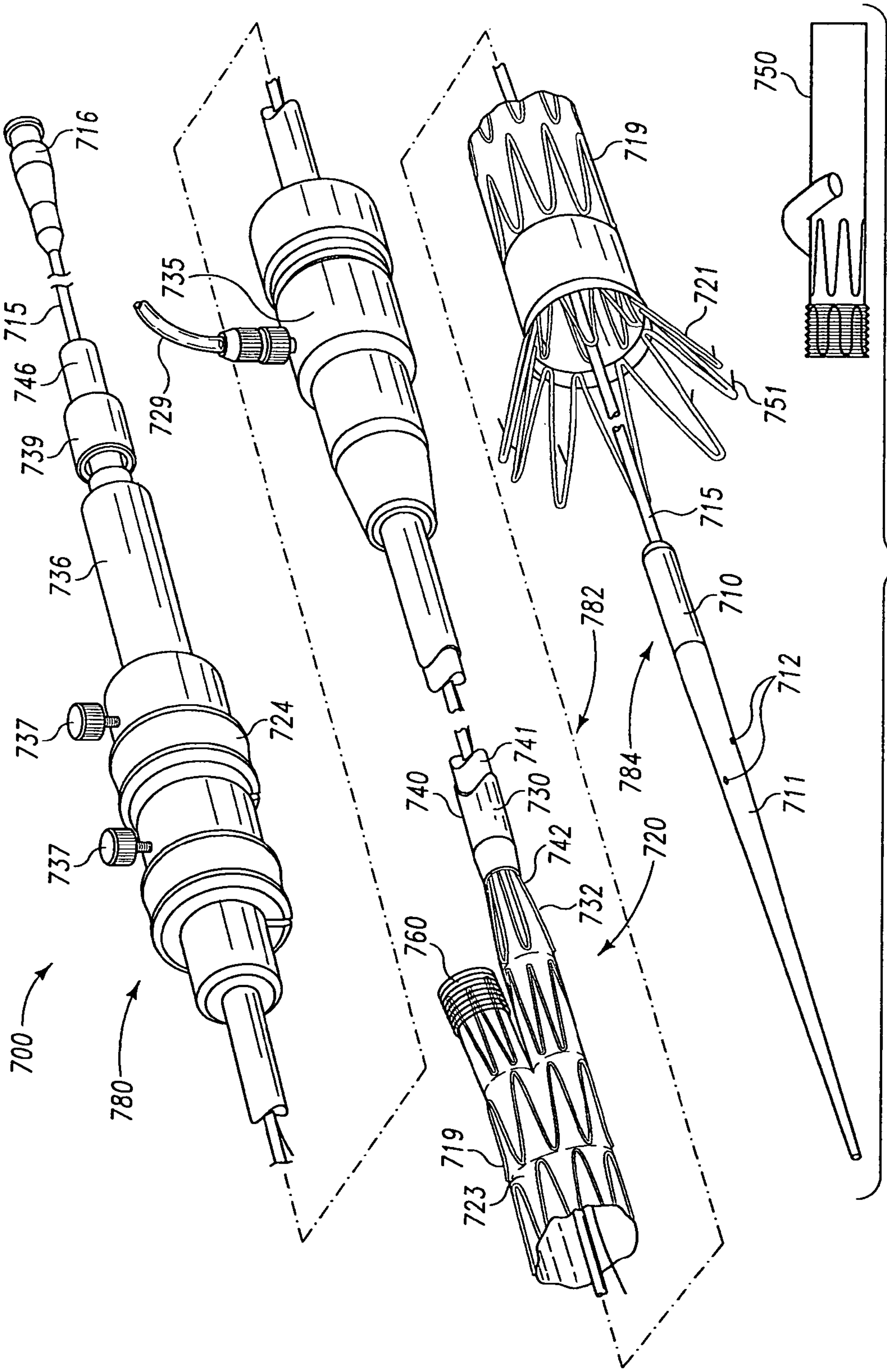
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FIG. 43

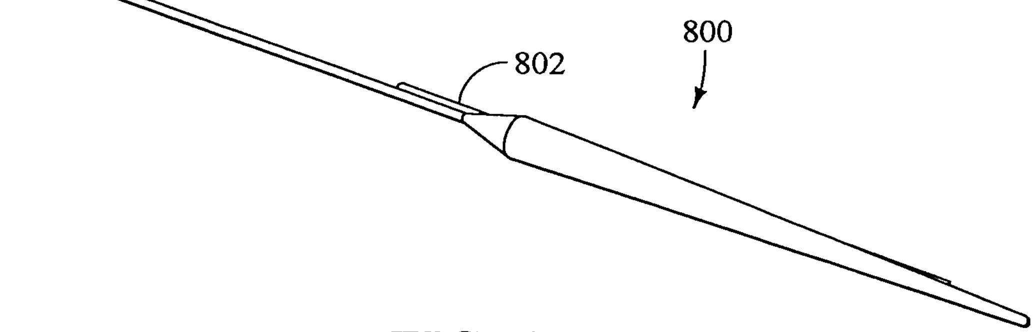

FIG. 44

BRANCHED VESSEL ENDOLUMINAL DEVICE

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 11/403,605, filed Apr. 13, 2006 (U.S. Patent Application Publication No. 2006/0247761), which is a continuation-in-part of U.S. patent application Ser. No. 10/756,803, filed Jan. 13, 2004 (U.S. Pat. No. 7,105,020), which claims the benefit of the filing date under 35 U.S.C. §119(e) of U.S. Provisional Patent Application Ser. No. 60/439,923, filed Jan. 14, 2003; U.S. Provisional Patent Application Ser. No. 60/478,107, filed Jun. 11, 2003; and U.S. Provisional Patent Application Ser. No. 60/510,636, filed Oct. 10, 2003, all of which are incorporated herein by reference.

This application also claims the benefit of the filing date under 35 U.S.C. §119(e) of U.S. Provisional Patent Application Ser. No. 60/671,410, filed Apr. 13, 2005, which is incorporated herein by reference.

TECHNICAL FIELD

This invention relates to prostheses for implantation within the human or animal body for the repair of damaged vessels, ducts or other physiological passageways.

BACKGROUND

Throughout this specification, when discussing the application of this invention to the aorta or other blood vessels, the term "distal" with respect to a prosthesis is intended to refer to a location that is, or a portion of the prosthesis that when implanted is, further downstream with respect to blood flow; the term "distally" means in the direction of blood flow or further downstream. The term "proximal" is intended to refer to a location that is, or a portion of the prosthesis that when implanted is, further upstream with respect to blood flow; the term "proximally" means in the direction opposite to the direction of blood flow or further upstream.

The functional vessels of human and animal bodies, such as blood vessels and ducts, occasionally weaken or even rupture. For example, the aortic wall can weaken, resulting in an aneurysm. Upon further exposure to hemodynamic forces, such an aneurysm can rupture. One study found that in Western European and Australian men who are between 60 and 75 years of age, aortic aneurysms greater than 29 mm in diameter are found in 6.9% of the population, and those greater than 40 mm are present in 1.8% of the population.

One surgical intervention for weakened, aneurysmal or ruptured vessels involves the use of an endoluminal prosthesis to provide some or all of the functionality of the original, healthy vessel and/or preserve any remaining vascular integrity by replacing a length of the existing vessel wall that spans the site of vessel failure.

It is preferable that these prostheses seal off the failed portion of the vessel. For weakened or aneurysmal vessels, even a small leak in the prosthesis may lead to the pressurization of or flow in the treated vessel, which aggravates the condition the prosthesis was intended to treat. A prosthesis of this type can, for example, treat aneurysms of the abdominal aortic, iliac, or branch vessels such as the renal arteries.

An endoluminal prosthesis can be of a unitary construction, or be comprised of multiple prosthetic modules. A modular prosthesis allows a surgeon to accommodate a wide variation in vessel morphology while reducing the necessary inventory of differently sized prostheses. For example, aortas vary in length, diameter and angulation between the renal artery region and the region of the aortic bifurcation. Prosthetic modules that fit each of these variables can be assembled to form a prosthesis, obviating the need for a custom prosthesis or large inventories of prostheses that accommodate all possible combinations of these variables. A modular system may also accommodate deployment by allowing the proper placement of one module before the deployment of an adjoining module.

Modular systems are typically assembled in situ by overlapping the tubular ends of the prosthetic modules so that the end of one module sits partially inside the other module, preferably forming circumferential apposition through the overlap region. This attachment process is called "tromboning." The connections between prosthetic modules are typically maintained by the friction forces at the overlap region and enhanced by the radial force exerted by the internal prosthetic module on the external prosthetic modules where the two overlap. The fit may be further enhanced by stents fixed to the modules at the overlap region.

A length of a vessel which may be treated by these prostheses may have one or more branch vessels, i.e. vessels anastomosed to the main vessel. The celiac, superior mesenteric, left common carotid and renal arteries, for example, are branch vessels of the aorta; the hypogastric artery is a branch vessel of the common iliac artery. If these branch vessels are blocked by the prosthesis, the original blood circulation is impeded, and the patient can suffer. If, for example, the celiac artery is blocked by the prosthesis, the patient can experience abdominal pain, weight loss, nausea, bloating and loose stools associated with mesenteric ischemia. The blockage of any branch vessel is usually associated with unpleasant or even life-threatening symptoms.

When treating a vessel with an endoluminal prosthesis, it is therefore preferable to preserve the original circulation by providing a prosthetic branch that extends from the main prosthetic module to a branch vessel so that the blood flow into the branch vessel is not impeded. For example, the aortic section of the Zenith® abdominal aortic prosthesis (Cook Incorporated, Bloomington, Ind.), described below, can be designed to extend above the renal arteries and to have prosthetic branches that extend into and provide flow to the renal arteries. Alternatively, the iliac branches of a bifurcated aortic prosthesis can be designed to extend into and provide flow to the corresponding hypogastric arteries. Branch extension prosthetic modules ("branch extensions") can form a tromboning connection to the prosthetic branch to extend further into the branch artery. Furthermore, some aneurysms extend into the branch vessels. Deploying prosthetic branches and branch extensions into these vessels may help prevent expansion and/or rupture of these aneurysms. High morbidity and mortality rates are associated with these aneurysms.

Typically, existing prosthetic branches have a straight y- or t-shaped connection to the main endoluminal graft. Examples of such prosthetic branches and their associated branch extensions are shown in U.S. Pat. Nos. 6,520,988 and 6,579,309. Some of these branch extensions and their associated prosthetic branches may dislocate, kink and/or cause poor hemodynamics. These problems may lead to thrombogenesis and endoleaks at the interconnection of the prosthetic branch and branch extension.

BRIEF SUMMARY

In one aspect, an endoluminal prosthesis may be provided and comprise a prosthetic trunk and first and second prosthetic branches. The prosthetic trunk comprises a trunk lumen extending therethrough and a trunk wall. The first prosthetic branch extends from the trunk wall and comprises a first branch lumen extending therethrough and a branch wall. The second prosthetic branch extends from the branch wall and comprises a second branch lumen. The first and second branch lumens are both in fluid communication with the trunk lumen through the trunk wall and the second branch lumen is in fluid communication with the first branch lumen through the branch wall.

At least one, and in some examples both, of the first and second prosthetic branches may be disposed longitudinally along and circumferentially about the prosthetic trunk. In some examples, one of the prosthetic branches may be disposed longitudinally along and circumferentially about the other of the prosthetic branches. The prosthetic branches may have any suitable shape. For example, at least one of the branches may be tapered.

In another aspect, an endoluminal prosthesis may be provided and comprise a prosthetic trunk and a stent attached to the prosthetic trunk. The prosthetic trunk comprises a trunk lumen extending therethrough, a wall, and an anastomosis in the wall. The stent has a generally tubular stent body that provides radial support to the prosthetic trunk. The stent body alternates endlessly about a longitudinal axis of the prosthetic trunk between a first stent pattern and a second stent pattern. The first stent pattern comprises a loop having a contour that contacts and supports the entire perimeter of the anastomosis. In some examples, the second stent pattern has a generally zigzag shape. The loop may have any contour that matches the contour of the anastomosis. In some examples, the loop has an ovoid shape.

In another aspect, an endoluminal prosthesis may be provided and comprise a prosthetic trunk having a trunk lumen, a prosthetic branch having a branch lumen, and a stent. The stent has a stent pattern that alternates endlessly about the perimeter of the stent between a first tubular stent region disposed about a first axis and a second tubular stent region disposed about a second axis. The first stent region is attached to and supports at least a portion of the prosthetic trunk and the second stent region is attached to and supports at least a portion of the prosthetic branch.

In some examples, the endless alternating stent pattern includes a generally zigzag shape. The first and second stent regions may have diameters that are generally the same, or they may have different diameters. The first stent axis and the second stent axis are arranged according to the arrangement of the prosthetic trunk and the prosthetic branch. For example, the first and second stent axes may be generally collinear. In some examples, the stent may have a figure-8 shape.

In some examples, the prosthetic branch may be disposed, at least in part, inside the prosthetic trunk lumen. Likewise, the prosthetic branch may be disposed, at least in part, outside the prosthetic trunk lumen. The stent may be disposed on the interior and/or exterior surface of the prosthetic trunk and the prosthetic branch. For example, at least a portion of the first stent region may be disposed on an interior surface of the prosthetic trunk. In these examples, at least a portion of the first stent region may be disposed on a surface of the prosthetic branch, for example an exterior surface of the prosthetic branch. In some examples, at least a portion of the second stent region may be disposed on an exterior surface of the prosthetic branch.

Other aspects of the present invention will become apparent in connection with the following description of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a schematic anterior view of an endoluminal prosthesis with a y-shaped prosthetic branch;

FIG. **2** shows a schematic anterior view of an endoluminal prosthesis with a helical prosthetic branch;

FIG. **3***a* shows a side view of an embodiment of an endoluminal prosthesis with a helical prosthetic branch;

FIG. **3***b* shows another side view of the embodiment of FIG. **3***a;*

FIG. **3***c* shows an embodiment of an extension module;

FIG. **4***a* shows a schematic top view of an embodiment of an endoluminal prosthesis;

FIG. **4***b* shows a schematic front view of the embodiment of FIG. **4***a;*

FIG. **4***c* shows a skeletal schematic front view of the embodiment of FIG. **4***a;*

FIGS. **5***a-d* show preferable steps for creating an enlarged anastomosis;

FIG. **6***a* shows a schematic anterior view of an embodiment of an endoluminal prosthesis;

FIG. **6***b* shows a skeletal view of the embodiment of FIG. **6***a;*

FIG. **7***a* shows a schematic anterior view of an embodiment of an endoluminal prosthesis;

FIG. **7***b* shows a top view the embodiment of FIG. **7***a;*

FIG. **8***a* shows an anterior view of an embodiment of an endoluminal prosthesis;

FIG. **8***b* shows a side view of the embodiment of FIG. **8***a;*

FIG. **8***c* shows another side view of the embodiment of FIG. **8***a;*

FIG. **8***d* shows a posterior view of the embodiment of FIG. **8***a;*

FIG. **9***a* shows a skeletal anterior view of an embodiment of an endoluminal prosthesis;

FIG. **9***b* shows a schematic anterior view of the embodiment of FIG. **9***a;*

FIG. **10***a* shows a schematic anterior view of an embodiment of an endoluminal prosthesis;

FIG. **10***b* shows a schematic top view of the embodiment of FIG. **10***a;*

FIGS. **11***a-c* show three views of an embodiment of an endoluminal prosthesis;

FIG. **12***a* shows a skeletal anterior view of an embodiment of an endoluminal prosthesis;

FIG. **12***b* shows a schematic anterior view of the embodiment of FIG. **12***a;*

FIG. **12***c* shows a schematic top view of the embodiment of FIG. **12***a;*

FIG. **13***a* shows a schematic anterior view of an embodiment of an endoluminal prosthesis that has crimps;

FIG. **13***b* shows a skeletal view of the embodiment of FIG. **13***a;*

FIG. **13***c* shows a schematic top view of the embodiment of FIG. **13***a;*

FIGS. **14***a-b* show two views of an embodiment of an endoluminal prosthesis;

FIG. **15***a* shows a modular prosthesis that has a prosthetic trunk module in the left iliac artery connected to a prosthetic branch in the hypogastric artery;

FIG. **15***b* shows the modular prosthesis of **15***a*, where the prosthetic trunk and aortic module are connected via an intervening prosthetic module;

FIG. **15***c* shows an intervening prosthetic module;

FIG. **16** shows a helical branch having annular stents;

FIG. **17** shows an annular stent sutured to the distal ostium of a helical branch;

FIG. **18** shows a helical branch having a helical stent;

FIG. **19** shows the helical stent coiled at the branch ostium;

FIG. **20** shows a stent at the branch anastomosis;

FIGS. **21***a*-*b* show two modified Z-stents that may be used to support, without obstructing, the branch-trunk anastomosis;

FIG. **21***c* shows a modified Z-stent that has a loop for supporting the branch trunk anastomosis;

FIG. **21***d* shows a modified Z-stent that has an asymmetrical bend for supporting the distal aspect of the branch-trunk anastomosis.

FIG. **22***a* shows the stents of FIGS. **21***a*-*b* attached to a graft and positioned to support a branch-trunk anastomosis;

FIG. **22***b* shows the stent of FIGS. **21***c* attached to a graft and positioned to support a branch-trunk anastomosis;

FIGS. **23***a*-*d* shows different views of a stent designed to maintain the shape of a branch-trunk anastomosis;

FIGS. **23***e*-*f* show the stent of FIGS. **23***a*-*d* affixed to the inside of a branch adjacent the branch-trunk anastomosis;

FIG. **24***a* shows a perspective view of a heat-setting fixture for forming the stent of FIGS. **23***a*-*d;*

FIG. **24***b* shows a plan view of a heat-setting fixture for forming the stent of FIGS. **23***a*-*d;*

FIG. **24***c* shows a perspective view of a part of the heat-setting fixture used to form the stent of FIGS. **23***a*-*d;*

FIG. **24***d* shows a side view of a heat-setting fixture used to form the stent of FIGS. **23***a*-*d;*

FIGS. **25**, **26**, and **27***a*-*e* show multiple prosthetic branches extending from a prosthetic trunk;

FIGS. **28***a*-*c* show an internal helical branch;

FIG. **29** shows a cross-section of a prosthesis having baffles affixed to an internal helical branch;

FIG. **30** shows an internal helical branch within a pocket;

FIG. **31** shows a cross-section of an internal helical branch within a pocket;

FIGS. **32***a*-*c* show thoracic prosthetic modules having one or more helical side branches;

FIGS. **33**-**36** show various perspective views of a prosthesis having a branch and fenestrations;

FIGS. **37** and **38** show skeletal views of the prosthesis of FIGS. **29**-**32**;

FIG. **39** shows a view of the prosthesis in the direction of arrow A of FIG. **38**;

FIG. **40** shows a view of the prosthesis in the direction of arrow B of FIG. **38**;

FIGS. **41***a*-*d* show various perspective views of an aortic prosthesis having a branch and fenestrations;

FIGS. **42***a*-*d* show various perspective views of an aortic prosthesis having a branch and fenestrations;

FIG. **43** shows an apparatus for deploying a bifurcated prosthesis; and

FIG. **44** shows a portion of a device used for deploying a branched vessel prosthesis.

DETAILED DESCRIPTION

Branch vessel prostheses may be formed with prosthetic branches that are disposed longitudinally and circumferentially with respect to the prosthetic trunk. Such prosthetic branches are termed "helical" prosthetic branches. A branch extension may be connected to the distal end of the helical prosthetic branch by tromboning.

The helical turn in the prosthetic branch may reduce the forces on the branch extension by shifting the hemodynamic forces from the prosthetic branch and the interconnection between the branch extension to the prosthetic trunk. This may help prevent the branch extension from pulling out under those forces. The helical turn may also allow a wider variation in the radial orientation ("angle of access") of the prosthetic trunk and may prevent kinking of the prosthetic branch or branch extension. This design may also improve the hemodynamics by, for example, promoting laminar flow.

To help understand this description, the following definitions are provided.

The term "prosthesis" means any replacement for a body part or function of that body part. It can also mean a device that enhances or adds functionality to a physiological system.

The term "endoluminal" describes objects that are found or can be placed inside a lumen in the human or animal body. A lumen can be an existing lumen or a lumen created by surgical intervention. This includes lumens such as blood vessels, parts of the gastrointestinal tract, ducts such as bile ducts, parts of the respiratory system, etc. An "endoluminal prosthesis" is thus a prosthesis that can be placed inside one of these lumens.

The term "stent" means any device or structure that adds rigidity, expansion force or support to a prosthesis. A Z-stent is a stent that has alternating struts and peaks (i.e., bends) and defines a generally cylindrical lumen. The "amplitude" of a Z-stent is the distance between two bends connected by a single strut. The "period" of a Z-stent is the total number of bends in the Z-stent divided by two, or the total number of struts divided by two.

The term "pull-out force" means the maximum force of resistance to partial or full dislocation provided by a modular prosthesis. The pull-out force of a prosthesis having two interconnected modules can be measured by an MTS Alliance RT/5® tensile testing machine (MTS Corporation, Eden Prairie, Minn.). The MTS machine is connected to a computer terminal that is used to control the machine, collect, and process the data. A pressurization pump system is attached to the load cell located on the tensile arm of the MTS machine. One end of the prosthesis is connected to the pressurization pump, which provides an internal pressure of 60 mm Hg to simulate the radial pressure exerted by blood upon the device when deployed in vivo. The other end of the prosthesis is sealed. The prosthesis is completely immersed in a 37° C. water bath during the testing to simulate mean human body temperature. The MTS machine pulls the devices at 0.1 mm increments until the devices are completely separated. The computer will record, inter alia, the highest force with which the modules resist separation, i.e. the pull-out force.

The term "endoleak" refers to a leak around or through an endoluminal prosthesis. Endoleaks can occur through the fabric of a prosthesis, through the interconnections of a modular prosthesis, or around the ends of the prosthesis, inter alia. Endoleakage may result in the repressurizing of an aneurysm.

The term "branch vessel" refers to a vessel that branches off from a main vessel. Examples are the celiac and renal arteries which are branch vessels to the aorta (i.e., the main vessel in this context). As another example, the hypogastric artery is a branch vessel to the common iliac, which is a main vessel in this context. Thus, it should be seen that "branch vessel" and "main vessel" are relative terms.

The term "prosthetic trunk" refers to a portion of a prosthesis that shunts blood through a main vessel. A "trunk lumen" runs through the prosthetic trunk.

The term "prosthetic branch" refers to a portion of a prosthesis that is anastomosed to the prosthetic trunk and shunts blood into and/or through a branch vessel.

A "peripheral prosthetic branch" is a prosthetic branch that is anastomosed to the side of a prosthetic trunk. This is distinguished from a "contralateral prosthetic branch," which is a prosthetic branch that results from a "pant leg" bifurcation. The bifurcation may be asymmetrical, i.e. the two "legs" may have different diameters or lengths.

The term "branch extension" refers to a prosthetic module that can be deployed within a branch vessel and connected to a prosthetic branch.

The term "helical" or "helically" describes a prosthetic branch that is oriented circumferentially about and longitudinally along a prosthetic trunk. "Helical" is not restricted to a regular helix or a full 360° circumferential turn.

"Longitudinally" refers to a direction, position or length substantially parallel with a longitudinal axis of a reference, and is the length-wise component of the helical orientation.

"Circumferentially" refers to a direction, position or length that encircles a longitudinal axis of reference, and is the radial component of a helical orientation. Circumferential is not restricted to a full 360° circumferential turn nor a constant radius.

"Anastomosis" refers to a connection between two lumens, such as the prosthetic trunk and prosthetic branch that puts the two in fluid communication with each other. "Anastomosing" refers to the process of forming an anastomosis.

The term "angle of incidence" refers to the angle of intersection of a longitudinal axis of a prosthetic branch and a line on the prosthetic trunk that runs longitudinally through the anastomosis.

The term "skew" refers to the angle of out-of-plane rotation of the prosthetic branch, relative to the longitudinal axis of the prosthetic trunk, as measured at or near the anastomosis.

The term "angle of access" refers to the acceptable range of radial orientation of the branched prosthesis about the longitudinal axis of the prosthetic trunk. Through that range, the distal ostium of the prosthetic branch is close enough to the branch vessel so that the branch extension can be properly deployed into the branch vessel to form a connection with the prosthetic branch.

FIG. **1** shows a schematic representation of a prosthetic branch **12** anastomosed to the prosthetic trunk **10** in a y-configuration. A branch extension **14** forms a tromboning connection with the prosthetic branch **12**. The branch extension **14** is positioned at a 45° angle **16** to the prosthetic trunk **10** to accommodate the anatomy in which the total prosthesis is designed to sit. The angle **16** of the branch extension **14** causes it to bear forces in the y-direction **15**, as a result of the blood pressure and momentum of the blood flow through the prosthetic branch **12** and branch extension **14**.

The connection between the branch extension **14** and the prosthetic branch **12** is maintained by friction forces. Therefore, if the forces in the y-direction **15** borne by the branch extension **14** exceed the friction forces that maintain the connection, the branch extension **14** may disconnect from the branch **12**. This is a dangerous outcome for the patient, as the disconnection can result in a repressurization of the region surrounding the prosthetic branch **12** and the prosthetic trunk **10**.

FIG. **2** shows a schematic representation of one embodiment of the present invention. In this embodiment, the prosthetic branch **22** is anastomosed to the prosthetic trunk **20**. A branch extension **25** forms a tromboning connection with the prosthetic branch **22**. The branch extension **25** is positioned at an about 60-70° angle **24** to the prosthetic trunk **20** to accommodate the anatomy in which the total prosthesis is designed to sit, although it can be placed at any suitable angle. The prosthetic branch **22** turns about the prosthetic trunk **20** to form a partial helix.

The angle **24** of the prosthetic branch **22** creates flow forces in the y-direction **23** as a result of the momentum of the blood flow through and physiological blood pressure in the branch **22**, just as in the prosthesis of FIG. **1**. However, unlike in FIG. **1**, the prosthetic branch **22** bears much of these y-forces and is supported by its attachment **27** to the prosthetic trunk **20**. Thus, the attachment **27** bears at least some of the y-direction forces instead of the load being placed on the interconnection **21** and the prosthetic branch **22**. This helps prevent a common failure mode known in branched prostheses. A prosthetic extension module **25** may form a tromboning interconnection with the prosthetic branch **22**.

FIG. **3***a* shows another embodiment of the present invention. This embodiment is suitable for deployment into the left iliac artery and branching into the left hypogastric artery, although it can be adapted for other vessels. An embodiment suitable for deployment into the right iliac artery could be a longitudinal mirror-image of the prosthesis **40** of FIG. **3***a*. The prosthesis **40** includes a prosthetic trunk **42** and a peripheral prosthetic branch **44**. For this prosthesis **40**, and the others discussed herein, the prosthetic branch **44** preferably curves around the anterior of the prosthetic trunk **42** as shown, although, as an alternative it may curve around the posterior of the prosthetic trunk **42**. The prosthetic branch **44** is in fluid communication with the prosthetic trunk **42** through the anastomosis **46**. The anastomosis **46** is preferably infundibular, i.e. funnel-shaped, as shown. This mimics a typical physiological anastomosis, and improves the hemodynamics of flow into the prosthetic branch **44**. The prosthetic branch **44** is preferably sutured to the prosthetic trunk **42** to form a blood-tight seal. The proximal end of the prosthetic trunk may have a scallop cut into it in order to facilitate deployment of the prosthesis **40**, described below.

The prosthetic trunk **42** is preferably made of woven polyester having a twill weave and a porosity of about 350 ml/min/cm^2 (available from Vascutek® Ltd., Renfrewshire, Scotland, UK). The prosthetic branch **44** is preferably made of seamless woven polyester. The prosthetic trunk **42** and prosthetic branch **44** can also be made of any other at least substantially biocompatible material including such fabrics as other polyester fabrics, polytetrafluoroethylene (PTFE), expanded PTFE, and other synthetic materials known to those of skill in the art. Naturally occurring biomaterials, such as collagen, are also highly desirable, particularly a derived collagen material known as extracellular matrix (ECM), such as small intestinal submucosa (SIS). Other examples of ECMs are pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, and dura mater. SIS is particularly useful, and can be made in the fashion described in U.S. Pat. No. 4,902,508 to Badylak et al.; U.S. Pat. No. 5,733,337 to Carr; U.S. Pat. No. 6,206,931 to Cook et al.; U.S. Pat. No. 6,358,284 to Fearnot et al.; 17 Nature Biotechnology 1083 (November 1999); and WIPO Publication WO 98/22158 of May 28, 1998, to Cook et al., which is the published application of PCT/US97/14855. All of these references are incorporated herein by reference. It is also preferable that the material is non-porous so that it does not leak or sweat under physiologic forces.

Graft materials may also include porous polymer sheet of a biocompatible material. Examples of biocompatible polymers from which porous sheets can be formed include polyesters, such as poly(ethylene terephthalate), polylactide, polyglycolide and copolymers thereof; fluorinated polymers, such as polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE) and poly(vinylidene fluoride); polysiloxanes, including polydimethyl siloxane; and polyurethanes, including polyetherurethanes, polyurethane ureas, polyetherurethane ureas, polyurethanes containing carbonate linkages and polyurethanes containing siloxane segments. In addition, materials that are not inherently biocompatible may be subjected to surface modifications in order to render the materials biocompatible. Examples of surface modifications include graft polymerization of biocompatible polymers from the material surface, coating of the surface with a crosslinked biocompatible polymer, chemical modification with biocompatible functional groups, and immobilization of a compatibilizing agent such as heparin or other substances. Thus, any polymer that may be formed into a porous sheet can be used to make a graft material, provided the final porous material is biocompatible. Polymers that can be formed into a porous sheet include polyolefins, polyacrylonitrile, nylons, polyaramids and polysulfones, in addition to polyesters, fluorinated polymers, polysiloxanes and polyurethanes as listed above. Preferably the porous sheet is made of one or more polymers that do not require treatment or modification to be biocompatible. More preferably, the porous sheet includes a biocompatible polyurethane. Examples of biocompatible polyurethanes include Thoralon® (Thoratec, Pleasanton, Calif.), Biospan®, Bionate®, Elasthane®, Pursil® And Carbosil® (Polymer Technology Group, Berkeley, Calif.).

Preferably the porous polymeric sheet contains the polyurethane Thoralon®. As described in U.S. Patent Application Publication No. 2002/0065552 A1, incorporated herein by reference, Thoralon® is a polyetherurethane urea blended with a siloxane-containing surface modifying additive. Specifically, the polymer is a mixture of base polymer BPS-215 and an additive SMA-300. The concentration of additive may be in the range of 0.5% to 5% by weight of the base polymer. The BPS-215 component (Thoratec) is a segmented polyether urethane urea containing a soft segment and a hard segment. The soft segment is made of polytetramethylene oxide (PTMO), and the hard segment is made from the reaction of 4,4'-diphenylmethane diisocyanate (MDI) and ethylene diamine (ED). The SMA-300 component (Thoratec) is a polyurethane comprising polydimethylsiloxane as a soft segment and the reaction product of MDI and 1,4-butanediol as a hard segment. A process for synthesizing SMA-300 is described, for example, in U.S. Pat. Nos. 4,861,830 and 4,675,361, which are incorporated herein by reference. A porous polymeric sheet can be formed from these two components by dissolving the base polymer and additive in a solvent such as dimethylacetamide (DMAC) and solidifying the mixture by solvent casting or by coagulation in a liquid that is a non-solvent for the base polymer and additive.

Thoralon® has been used in certain vascular applications and is characterized by thromboresistance, high tensile strength, low water absorption, low critical surface tension, and good flex life. Thoralon® is believed to be biostable and to be useful in vivo in long term blood contacting applications requiring biostability and leak resistance. Because of its flexibility, Thoralon® is useful in larger vessels, such as the abdominal aorta, where elasticity and compliance is beneficial.

In addition to Thoralon®, other polyurethane ureas may be used as a porous sheet. For example, the BPS-215 component with a MDI/PTMO mole ratio ranging from about 1.0 to about 2.5 may be used. Such polyurethane ureas preferably include a soft segment and include a hard segment formed from a diisocyanate and diamine. For example, polyurethane ureas with soft segments such as polyethylene oxide, polypropylene oxide, polycarbonate, polyolefin, polysiloxane (i.e. polydimethylsiloxane), and other polyether soft segments made from higher homologous series of diols may be used. Mixtures of any of the soft segments may also be used. The soft segments also may have either alcohol end groups or amine end groups. The molecular weight of the soft segments may vary from about 500 to about 5,000 g/mole.

The diisocyanate used as a component of the hard segment may be represented by the formula OCN—R—NCO, where —R— may be aliphatic, aromatic, cycloaliphatic or a mixture of aliphatic and aromatic moieties. Examples of diisocyanates include tetramethylene diisocyanate, hexamethylene diisocyanate, trimethyhexamethylene diisocyanate, tetramethylxylylene diisocyanate, 4,4'-decyclohexylmethane diisocyanate, dimer acid diisocyanate, isophorone diisocyanate, metaxylene diisocyanate, diethylbenzene diisocyanate, decamethylene 1,10 diisocyanate, cyclohexylene 1,2-diisocyanate, 2,4-toluene diisocyanate, 2,6-toluene diisocyanate, xylene diisocyanate, m-phenylene diisocyanate, hexahydrotolylene diisocyanate (and isomers), naphthylene-1,5-diisocyanate, 1-methoxyphenyl 2,4-diisocyanate, 4,4'-biphenylene diisocyanate, 3,3-dimethoxy-4,4'-biphenyl diisocyanate and mixtures thereof.

The diamine used as a component of the hard segment includes aliphatic amines, aromatic amines and amines containing both aliphatic and aromatic moieties. For example, diamines include ethylene diamine, propane diamines, butanediamines, hexanediamines, pentane diamines, heptane diamines, octane diamines, m-xylylene diamine, 1,4-cyclohexane diamine, 2-methypentamethylene diamine, 4,4'-methylene dianiline, and mixtures thereof. The amines may also contain oxygen and/or halogen atoms in their structures.

In addition to polyurethane ureas, other polyurethanes, preferably those having a chain extended with diols, may be used as a porous sheet. Polyurethanes modified with cationic, anionic and aliphatic side chains may also be used. See, for example, U.S. Pat. No. 5,017,664. Polyurethanes may need to be dissolved in solvents such as dimethyl formamide, tetrahydrofuran, dimethyacetamide, dimethyl sulfoxide, or mixtures thereof.

The soft segments of these polyurethanes may contain any of the soft segments mentioned above, such as polytetramethylene oxide, polyethylene oxide, polypropylene oxide, polycarbonate, polyolefin, polysiloxane (i.e., polydimethylsiloxane), other polyether soft segments made from higher homologous series of diols, and mixtures of these soft segments. The soft segments may have amine end groups or alcohol end groups.

The hard segment may be formed from any of the diisocyantes listed above, such as 4,4'-diphenylmethane diisocyanate, tetramethylene diisocyanate, hexamethylene diisocyanate, trimethyhexamethylene diisocyanate, tetramethylxylylene diisocyanate, 4,4'-decyclohexylmethane diisocyanate, dimer acid diisocyanate, isophorone diisocyanate, metaxylene diisocyanate, diethylbenzene diisocyanate, decamethylene 1,10 diisocyanate, cyclohexylene 1,2-diisocyanate, 2,4-toluene diisocyanate, 2,6-toluene diisocyanate, xylene diisocyanate, m-phenylene diisocyanate, hexahydrotolylene diisocyanate (and isomers), naphthylene-1,5-diisocyanate, 1-methoxyphenyl 2,4-diisocyanate, 4,4'-biphenylene diisocyanate, 3,3-dimethoxy-4,4'-biphenyl diisocyanate and mixtures thereof.

The hard segment may be formed from one or more polyols. Polyols may be aliphatic, aromatic, cycloaliphatic or may contain a mixture of aliphatic and aromatic moieties. For example, the polyol may be ethylene glycol, diethylene glycol, triethylene glycol, 1,4-butanediol, neopentyl alcohol, 1,6-hexanediol, 1,8-octanediol, propylene glycols, 2,3-butylene glycol, dipropylene glycol, dibutylene glycol, glycerol, or mixtures thereof.

In addition, the polyurethanes may also be end-capped with surface active end groups, such as, for example, polydimethylsiloxane, fluoropolymers, polyolefin, polyethylene oxide, or other suitable groups. See, for example the surface active end groups disclosed in U.S. Pat. No. 5,589,563, which is incorporated herein by reference.

The porous polymeric sheet may contain a polyurethane having siloxane segments, also referred to as a siloxane-polyurethane. Examples of polyurethanes containing siloxane segments include polyether siloxane-polyurethanes, polycarbonate siloxane-polyurethanes, and siloxane-polyurethane ureas. Specifically, examples of siloxane-polyurethane include polymers such as Elast-Eon 2® and Elast-Eon 3® (Aortech Biomaterials, Victoria, Australia); polytetramethyleneoxide (PTMO) and polydimethylsiloxane (PDMS) polyether-based aromatic siloxane-polyurethanes such as Pursil®-10, -20, and -40 TSPU; PTMO and PDMS polyether-based aliphatic siloxane-polyurethanes such as Pursil AL-5® and AL-10 TSPU®; aliphatic, hydroxy-terminated polycarbonate and PDMS polycarbonate-based siloxane-polyurethanes such as Carbosil®-10, -20, and -40 TSPU (all available from Polymer Technology Group). The Pursil®, Pursil-AL®, and Carbosil® polymers are thermoplastic elastomer urethane copolymers containing siloxane in the soft segment, and the percent siloxane in the copolymer is referred to in the grade name. For example, Pursil-10® contains 10% siloxane. These polymers are synthesized through a multi-step bulk synthesis in which PDMS is incorporated into the polymer soft segment with PTMO (Pursil®) or an aliphatic hydroxy-terminated polycarbonate (Carbosil®). The hard segment consists of the reaction product of an aromatic diisocyanate, MDI, with a low molecular weight glycol chain extender. In the case of Pursil-AL® the hard segment is synthesized from an aliphatic diisocyanate. The polymer chains are then terminated with a siloxane or other surface modifying end group. Siloxane-polyurethanes typically have a relatively low glass transition temperature, which provides for polymeric materials having increased flexibility relative to many conventional materials. In addition, the siloxane-polyurethane can exhibit high hydrolytic and oxidative stability, including improved resistance to environmental stress cracking. Examples of siloxane-polyurethanes are disclosed in U.S. Patent Application Publication No. 2002/0187288 A1, which is incorporated herein by reference.

The porous polymer sheet may contain polytetrafluoroethylene or expanded polytetraffluoroethylene (ePTFE). Films or sheets of ePTFE are typically porous without the need for further processing. The structure of ePTFE can be characterized as containing nodes connected by fibrils. Porous ePTFE can be formed, for example, by blending PTFE with an organic lubricant and compressing it under relatively low pressure. Using a ram type extruder, the compressed polymer is then extruded through a die, and the lubricant is removed from the extruded polymer by drying or other extraction method. The dried material is then rapidly stretched and/or expanded at elevated temperatures. This process can provide for ePTFE having a microstructure characterized by elongated nodes interconnected by fibrils. Typically, the nodes are oriented with their elongated axis perpendicular to the direction of stretch. After stretching, the porous polymer is sintered by heating it to a temperature above its crystalline melting point while maintaining the material in its stretched condition. This can be considered as an amorphous locking process for permanently setting the microstructure in its expanded or stretched configuration. The structure and porosity of ePTFE is disclosed, for example, in U.S. Pat. Nos. 6,547,815 B2; 5,980,799; and 3,953,566; all of which are incorporated herein by reference. Structures of porous hollow fibers can be formed from PTFE, and these porous hollow fibers can be assembled to provide a cohesive porous sheet. Porous hollow fibers containing PTFE are disclosed, for example, in U.S. Pat. No. 5,024,671, which is incorporated herein by reference.

Polymers can be processed to be porous sheets using standard processing methods, including solvent-based processes such as casting, spraying and dipping, and melt extrusion processes. Extractable pore forming agents can be used during processing to produce porous sheets. Examples of extractable pore forming agents include inorganic salts such as potassium chloride (KCl) and sodium chloride (NaCl), organic salts, and polymers such as poly(ethylene glycol) (PEG) and polyvinylpyrrolidone (PVP). Pore forming agents may have a particle size from about 10 μm to about 500 μm, from about 20 μm to about 100 μm, and from about 10 μm to about 40 μm. The amount of pore forming agent relative to the polymer may be from about 20 percent by weight (wt %) to about 90 wt %, and from about 40 wt % to about 70 wt %. These sizes and amounts of pore forming agents can provide for a high degree of porosity following extraction of the pore forming agent. The porosity can be from about 20 wt % to about 90 wt %, and from about 40 wt % to about 70 wt % of the final product.

Porous sheets may be in the form of a microporous, open-celled structure in which the pores are substantially interconnected. Microporous structures can be formed by extrusion of a mixture of polymer and one or more blowing agents. Microcellular polymeric foams can be produced by exposing the polymer to super-critical CO_2 under high temperature and pressure to saturate the polymer with the super-critical CO_2, and then cooling the polymer. Microcellular foams can be produced as described, for example, in U.S. Pat. Nos. 4,473,665 and 5,160,674, which are incorporated herein by reference. The foaming process can be carried out on extruded polymer tube by first dissolving an inert gas such as nitrogen or CO_2 under pressure into the polymer, and then forming microvoids by quickly decreasing the solubility of the gas in the polymer by changing the pressure or temperature, thus inducing thermodynamic instability. Examples of microporous polymeric structures are disclosed, for example, in U.S. Pat. No. 6,702,849 B1, which is incorporated herein by reference.

Porous Thoralon® can be formed by mixing the polyetherurethane urea, the surface modifying additive and a particulate substance in a solvent. Preferably the particulate is insoluble in the solvent, and the particulate may be any of a variety of different particulates or pore forming agents. For example, the solvent may be DMAC, and the particulate may be an inorganic salt. The composition can contain from about 5 wt % to about 40 wt % polymer, and different levels of polymer within the range can be used to fine tune the viscosity needed for a given process. The composition can contain less than 5 wt % polymer for some spray application embodiments. The particulates can be mixed into the composition. For example, the mixing can be performed with a spinning blade mixer for about an hour under ambient pressure and in a temperature range of about 18° C. to about 27° C. The entire composition can be cast as a sheet, or coated onto an article such as a mandrel or a mold. In one example, the composition can be dried to remove the solvent, and then the dried material can be soaked in distilled water to dissolve the particulates and leave pores in the material. In another example, the composition can be coagulated in a bath of distilled water. Since the polymer is insoluble in the water, it will rapidly solidify, trapping some or all of the particulates. The particulates can then dissolve from the polymer, leaving pores in the material. It may be desirable to use warm water for the extraction, for example water at a temperature of about 60° C. The resulting void-to-volume ratio can be substantially equal to the ratio of salt volume to the volume of the polymer plus the salt. The resulting pore diameter can also be substantially equal to the diameter of the salt grains.

The porous polymer sheet can have a void-to-volume ratio from about 0.40 to about 0.90. Preferably the void-to-volume ratio is from about 0.65 to about 0.80. Void-to-volume ratio is defined as the volume of the pores divided by the total volume of the polymeric layer including the volume of the pores. The void-to-volume ratio can be measured using the protocol described in AAMI (Association for the Advancement of Medical Instrumentation) VP20-1994, Cardiovascular Implants—Vascular Prosthesis section 8.2.1.2, Method for Gravimetric Determination of Porosity. The pores in the polymer can have an average pore diameter from about 1 micron to about 400 microns. Preferably the average pore diameter is from about 1 micron to about 100 microns, and more preferably is from about 1 micron to about 10 microns. The average pore diameter is measured based on images from a scanning electron microscope (SEM). Formation of porous Thoralon® is described, for example, in U.S. Patent Application Publication Nos. 2003/0114917 A1 and 2003/0149471 A1, both of which are incorporated herein by reference.

The prosthetic branch **44** is preferably, but not necessarily, connected to a branch extension. The prosthetic branch **44** and the branch extension **55** preferably have complementary annular crimps **48**. Crimping decreases the risk of kinking, thereby helping preserve the patency of the prosthesis. Complementary crimping or other types of projections at the tromboning interconnection also help maintain the seal and prevent pull-out. Complementary projections on the overlapping modules tend to engage each other to maximize the surface contact between opposing contact surfaces. The prosthetic branch **44** and the branch extension **55** may be only partially crimped.

The crimps shown in FIG. **3***a* may be created by mounting the prosthetic branch **44**, for example, over a mandrel of substantially the same diameter. A thread, wire or other filament is wrapped helically around the prosthetic branch **44**. The assembly as described is then heated to a temperature of 138° C. for eight (8) hours. Other temperatures can be used. Typically, the higher the temperature, the shorter the time required for adequate crimping, and vice versa. This induces helical crimping in the wrapped portion of the prosthesis. Annular crimps can also be generated by attaching annular filaments to the prosthetic branch **44** and performing the other steps of this process. The crimp peaks can be spaced by any suitable distance, preferably so that there are about 5 crimp peaks per 10 mm. The crimped interconnection and methods for producing crimps are described in greater detail in U.S. patent application entitled "Endoluminal Prosthesis With Interconnectable Modules," Ser. No. 10/962,001, filed Oct. 8, 2004 (U.S. Patent Application Publication No. 2005/0113905), which is incorporated herein by reference.

The preferred size and shape of the prosthetic module **40** depends on the anatomy in which it is to be implanted and the corresponding module to which this prosthetic module **40** will be connected. Physiological variables, deployment characteristics, and other factors also contribute to the determination of proper size and shape of the prosthetic trunk. The prosthetic trunk **42**, if designed for deployment into the iliac artery, preferably has a 12 mm diameter through its length, as shown, but may have a taper, turn or any other suitable geometry. The dimensions of any of the prostheses mentioned herein are only provided as an example, and will preferably be altered to match a particular patient's anatomy.

The stents **50**, **52**, **53** maintain the patency of the prosthesis and ensure adequate sealing against the surrounding vascular tissue. One goal for stent design and placement, whether internal or external, is to prevent metal-to-metal contact points, prevent contact between two different types of alloys and minimize micromotion. Stent sizing, spacing and design should be determined so that there is no stent-to-stent contact even in tortuous anatomy. Stents are preferably placed to maximize prosthesis flexibility while maintaining patency, as well as reduce material wear and stent fatigue. Furthermore, it is preferable that the stents do not interfere with the prosthetic branch, that they minimize the potential for galvanic corrosion and ensure adequate joint stability. Stent amplitude, spacing and stagger are preferably optimized for each prosthesis design. Any of the stents mentioned herein may have barbs to help decrease prosthesis migration.

The Z-stent design is preferred for straight sections of the aorta; it provides both significant radial force as well as some longitudinal support. In tortuous anatomy, branches or fenestrations, it may be preferable to use alternative stents or modifications to the Z-stent design to avoid stent-to-stent contact. Furthermore, in complex anatomic situations, external stents have the potential to become intertwined with the wires and other devices utilized to ensure branch vessel access, sealing and fixation. In some instance it may be desirable to affix some of the stents to the internal surface of the prosthesis. The Z-stents mentioned herein are preferably made from standard medical grade stainless steel and are soldered using silver standard solder (0 lead/0 tin); other stents may be made from nitinol or other shape-memory metal.

As shown in FIG. **3***a*, stents **50**, **52**, **53** are preferably affixed to the prosthesis **40** both internally **50** and externally **52**, **53**. Preferably Gianturco-type Z-stents of either 14 or 16 gauge (commercially available from Cook Incorporated, Bloomington, Ind.) are employed, as shown. The stents **50**, **52**, **53** are preferably spaced 4 mm from each other, as measured peak-to-peak. The peaks **59** are preferably staggered for minimal contact with each other. The stents **50**, **52** preferably have a 14 mm amplitude **41**. The stent **53** nearest to the anastomosis **46** has a 22 mm amplitude, except near the anastomosis **46**, where the amplitude is preferably 11 mm so that it does not interfere with the anastomosis **46**. This stent **53** may be affixed internally. These stents are preferably self-expanding, but one or more may be balloon expandable.

At least one stent (not shown) is associated with the prosthetic branch **44**; it is preferably attached just below the proximal seam **47** of the prosthetic branch **44**. The stent is employed to keep the anastomosis **46** open and to prevent kinking upon bending of the prosthetic branch **44**. Prolene® 5-0 sutures (not shown) are preferably used for the distal sealing stent **50** while polyester 4-0 sutures (not shown) are used for all other stents **52**, **53**. Two conventional sutures are preferably tied to each strut **57**, and one suture is preferably tied at each peak **59**.

The angle of incidence of the prosthetic branch **44** is preferably about 20° to about 60°, and more preferably about 45° with respect to the prosthetic trunk **42**; the skew is preferably about 0° to about 30° at the anastomosis **46**. The prosthetic branch **44** is preferably anchored to prosthetic trunk **42** by three spaced sutures (not shown) no closer than about 4 mm from the anastomosis **46**.

Standard endoluminal techniques may be used to deploy this prosthesis, as described below in further detail. An 18 French sheath may be used, unless loading issues warrant a larger sheath such as a 20 French. Standard radiopaque gold markers (Cook Incorporated, Bloomington, Ind.) are preferably used to assist graft orientation when the prosthesis is viewed through a fluoroscope.

FIG. **3***b* is an alternative perspective of the prosthesis **40** of FIG. **3***a*. This shows the shape of the anastomosis **46**. The size and shape of the anastomosis **46** may promote laminar flow and other positive hemodynamic characteristics. One method for creating this kind of anastomosis is described below in reference to FIG. **5**.

After the prosthesis **40** is implanted, the distal ostium **54** of the prosthetic branch **44** is preferably positioned in the vicinity of the main vessel-branch vessel anastomosis. Then the branch extension **55**, shown in FIG. **3***c*, can be implanted so that it forms a tromboning connection with the prosthetic branch **44**. There is preferably a 1 mm or less difference in diameter at the interconnection between the distal ostium **54** of the prosthetic branch **44** and the branch extension **55** to encourage a sealing interconnection. The branch extension **55** may have stents, preferably internal stents, which are less likely to interfere with the seal or fit between corresponding crimps **48**. The branch extension **55** can also be a properly sized Viabahn® Endoprosthesis (W. L. Gore & Associates, Inc., Newark, Del.), a Fluency® self-expanding nitinol stent graft (Bard, Tempe, Ariz.) or an iCast® covered stent (Atrium, Hudson, N.H.). One or both ends of the branch extension can have a nitinol ring or coil; a proximal ring or coil preferably engages a corresponding nitinol ring or coil in the helical branch of FIG. **17**. The stent can be covered, uncovered or partially covered with PTFE, ePTFE, woven polyester, Thoralon® or other materials. The stents may be self-expanding or balloon-expandable.

FIG. **4***a* shows a top view of a prosthesis **60** with a prosthetic trunk **62** and prosthetic branch **64**. This prosthesis **60** is designed to be deployed into the right common iliac artery and branch to the right hypogastric artery, although can be adapted for deployment into other vessels. The prosthetic branch **64** is positioned longitudinally along and circumferentially about an external surface of the prosthetic trunk **62**, i.e. generally in the form of a helix about the longitudinal axis **75**. The prosthetic branch **64** shown in FIG. **4***a* makes a 195° (or slightly more than one-half the circumference) turn about the prosthetic trunk **62** as measured from the midpoint **77** of the anastomosis to the midpoint of the distal ostium **65**, as shown in FIG. **4***a*. This perspective shows that the distal ostium **65** of the prosthetic branch **64** is beveled by 30°. This may increase the access angle and ease of insertion for the branch extension. A side view of the prosthesis **60** of FIG. **4***a* is shown in FIGS. **4***b* and **4***c*. This prosthesis **60** has three external Z-stents **66** near the prosthetic trunk **62**. FIG. **4***c*, a skeletal view of the prosthesis, shows an internal Z-stent **70** that straddles the anastomosis **68** and an internal stent **72** on the distal terminus **74**. One method for forming the enlarged anastomosis **68** is shown in FIGS. **5***a-d*. The Z-stent **70** that is adjacent the anastomosis may be attached to the graft internally or externally. The flexibility of the prosthetic trunk **62** may be increased by annular or helical crimping of the fabric between the stents of the prosthetic trunk **62**.

FIG. **5***a* shows a process for creating an enlarged or "teardrop" anastomosis. The starting material for the prosthetic branch **80** is typically a tubular section of polyester prosthesis fabric. The tubular length of prosthesis fabric may also be flared towards the proximal end **84**. The proximal end **84** of the prosthetic branch **80** can be cut at a right angle to the longitudinal axis of the prosthetic branch **80**, as shown, or can be beveled or otherwise shaped. The prosthetic branch **80** is cut along a line **82** at its proximal end **84**. The line **82** does not have to be parallel to the axis of the tube. Then, as shown in FIG. **5***b*, the proximal end **84** is splayed. Following splaying, the proximal end **84** can be further shaped to form a new perimeter **86**, as shown in FIG. **5***c*. The splayed perimeter **89** of the proximal end **84** shown in FIG. **5***b* is preferably sewn to the perimeter of a fenestration (not shown) in the prosthetic trunk **88** of a shape and size to match the splayed perimeter **89**, as shown in FIG. **5***d*. The seam is preferably blood-tight. The fenestration can be oriented in any way relative to the axis of the prosthetic trunk **88** to skew the prosthetic branch **80**. The prosthetic branch **80** is then preferably attached to the prosthetic trunk **88** such that it is positioned longitudinally and circumferentially in relation to the prosthetic trunk **88**.

FIG. **6***a* shows a prosthesis **90** with two helical peripheral prosthetic branches **92**, **94** extending therefrom. This prosthesis is designed to be positioned within the aorta so that the prosthetic branches **92**, **94** can extend to the renal arteries, although this prosthesis design can be adapted for use in other vessels. Branch extensions can then be positioned within the renal arteries so that they form a tromboning connection with the prosthetic branches **92**, **94**. The uncovered stent **96** is a suprarenal fixation stent which may have barbs (not shown). A skeletal view of the prosthesis **90** of FIG. **6***a* is shown in FIG. **6***b*. The stent **95** closest to the distal end **93** of the prosthesis **90** is preferably attached internally, as is the stent **97** near the anastomoses **98**. The anastomoses **98** can be as shown or can be the enlarged anastomosis described above with reference to FIG. **5**. The prosthetic branches **92**, **94** may slope away from the distal end **93** of the prosthesis **90**, as shown, or towards the distal end **93** of the prosthesis **90**. Stents (not shown) may be used to keep the prosthetic branches **92**, **94** patent. Additional prosthetic branches may be anastomosed to the prosthesis **90** to shunt blood to the celiac, SMA, and/or other branch vessels.

In FIG. **7***a*, a skeletal view of a prosthesis **110** with a helical contralateral prosthetic branch **112** is shown. The prosthesis **110** is designed for deployment into a right iliac artery and branching into the hypogastric. Distally to the bifurcation **116**, the length of the prosthetic branch **112** is positioned longitudinally and circumferentially with respect to the prosthetic trunk **114** and is seamless along its length. The longitudinal and circumferential placement of the prosthetic branch **112** is secured with one or more sutures (not shown) near and more proximally from the distal ostium **120** of the prosthetic branch **112**. For this and other prostheses, the prosthetic branch **112** may extend into the prosthetic trunk **114**, proximally to the bifurcation **116**, such that the branch lumen (not shown) originates within the lumen (not shown) of the prosthetic trunk **114**.

The prosthesis **110** is preferably made from woven polyester described above; the prosthetic branch **112** is preferably crimped. The stents are attached using Prolene® 5-0 sutures. Gold markers (not shown) are preferably attached to the prosthesis **110** in various locations to indicate the position and orientation of the prosthesis **110** under a fluoroscope.

An internal stent **123** is used in the prosthetic branch **112** slightly below the seam **118** and near the bifurcation **116** to keep the prosthetic branch **112** patent and prevent kinking; this stent **123** is preferably internal to the prosthesis **110**, but can also be placed externally. The stent **123** is preferably 6 gauge in diameter, has an amplitude of 8 mm and a period of 6. Two prosthetic trunk stents **126** are attached proximally to the bifurcation **116**; these stents **126** preferably have a 17 mm amplitude, a diameter of 20 gauge and a period of 9. The prosthesis **110** also has four stents **128** placed distally to the bifurcation **116**; these stents **128** preferably have a 14 mm amplitude, a diameter of 14 gauge and a period of 7. The stents **126**, **128** are spaced about 4 mm from each other and the peaks **127** of the distal stents **128** are staggered to minimize contact between them. The two most distal stents **125** on the prosthetic trunk **114** can be affixed internally to prevent interference with the deployment of the branch extension.

The distal ostium **120** of the prosthetic branch **112** is preferably 6 mm in diameter. The distal end **122** of the prosthetic trunk **114** is preferably 14 mm in diameter; the proximal ostium **130** of the prosthetic trunk **114** is preferably 20 mm in diameter. The diameter of the prosthetic trunk **114** may be reduced to 12 mm. The distance between the proximal end **124** of the prosthetic trunk **114** to the distal end **132** of the prosthetic branch **112** is preferably about 65 mm. These dimensions are only provided as an example and may be varied to match the anatomy of a specific patient.

FIG. **7***b* shows a top view of the prosthesis of FIG. **7***a*. The prosthetic branch **112** preferably turns 151° about the longitudinal axis **139** of the prosthetic trunk **114**.

FIGS. **8***a-d* show different perspectives of a contralateral branched prosthesis **140** similar to the branched prosthesis described in FIGS. **7***a-b*. This prosthesis **140** is designed for deployment into a right iliac artery and branching into the right hypogastric. Radiopaque markers **142** are sewn to the prosthesis **140**. The prosthetic branch **144** is preferably made of woven, crimped polyester. In FIG. **8***d*, the seam **146** between the prosthetic branch **144** and the prosthetic trunk **141** is evident. The stent (not shown) nearest to the distal end **145** of the prosthetic trunk **141** is attached internally. Any or all of the external stents **143** positioned distally to the seam **146** may be moved internally. Also, the prosthetic branch **144** at the seam **146** could be beveled; this would provide a larger ostium.

FIGS. **9***a-b* show an additional embodiment of the contralateral branched prosthesis similar to that described in reference to FIG. **7**. FIG. **9***a* is a skeletal view, showing both the internal stent **160** and the external stents **162**. The prosthesis of FIG. **9** has a prosthetic branch **161** that extends vertically down from the bifurcation **168** and then bends around the prosthetic trunk **170**. The second-most distal stent **163** can also be affixed internally.

FIGS. **10***a-b* are schematic representations of the prosthesis described in reference to FIGS. **11***a-c*, below, and show another embodiment of a contralateral branched prosthesis **210**. This prosthesis **210** is designed for deployment into the common iliac and branching into the hypogastric, although it can be adapted for use in any branched vessel. The longitudinal and circumferential placement of the prosthetic branch **212** is secured with one or more sutures near the distal end **220** of the prosthetic branch **212** and more proximally from the distal end **220**. The prosthesis **210** is preferably made from woven polyester; the prosthetic branch **212** is preferably made from crimped polyester. FIG. **10***b* shows the relative orientation of the prosthetic branch **212** to the prosthetic trunk **214**; the prosthetic branch **212** preferably turns 151° helically around the prosthetic trunk **214**.

FIGS. **11***a-c* show a branched contralateral prosthesis **211** suitable for deployment within the right iliac artery and branching into the hypogastric artery. The prosthetic trunk **233** has a proximal section **217** with a diameter of about 20 mm and a distal section **219** with a diameter of about 12 mm. The prosthetic branch **213** originates at the 20 mm diameter proximal section **217** and has a helical path about the 12 mm distal section **219**. The helical path of the prosthetic branch **213** is approximately 180° in circumference and approximately 60 mm longitudinally from the seam **225**. The pitch is preferably about 45°. The prosthetic branch **213** is preferably 6 mm in diameter through its length and constructed of crimped polyester graft material.

An internal stent **223**, shown in FIG. **11***a*, slightly overlaps the seam **225** so that it is flush with the bifurcation **227** to keep the ostium open and prevent kinking upon bending of the prosthetic branch **213**. This stent **223** is preferably attached to the internal surface of the prosthesis **211**, but can also be placed externally. The stent **223** is preferably 6 gauge in thickness, 8 mm in height and preferably has a period of 6. Two stents **226** are attached proximally to the bifurcation **227**; these stents **226** preferably have an 18 mm amplitude, a diameter of 20 gauge and a period of 10, and are spaced from each other by 2 mm. The prosthesis **211** also has four stents **228** placed distally to the bifurcation **227**; these stents **228** have a preferred **14** gauge thickness, 14 mm amplitude, a period of 7, and are spaced by 3 mm. The two most distal stents **229** are preferably attached internally. The stents are preferably attached using Prolene® 5-0. Gold markers **215** are attached to the prosthesis **211** in various locations to indicate the position of the prosthesis **211** under a fluoroscope.

The distal ostium **220** of the prosthetic branch **213** is preferably 6 mm in diameter; the distal end **222** of the prosthetic trunk **214** is preferably 12 mm in diameter; the proximal ostium **230** of the prosthetic trunk **214** is preferably 20 mm in diameter. The dimensions of this prosthesis **211**, like the other prostheses described herein, are preferably matched to the anatomy of a specific patient. The peaks **231** of the prosthetic trunk stents **226**, **228** are staggered to minimize contact between them. The distance between the proximal end **224** of the prosthetic trunk **214** to the distal ostium **222** of the prosthetic branch **212** is preferably about 70 mm. Deployment of this prosthesis **211** is made easier by the helical design, which allows the "angle of access" to be about 3 times greater than in y- or t-shaped branched prostheses.

FIG. **12***a* shows a skeletal view of a peripheral branched prosthesis **250**. The prosthetic branch **252** of this prosthesis **250** extends at an angle from the side of the prosthetic trunk **254** and then bends back to the prosthetic trunk **254** where it is affixed with sutures. There is a gap **256** between the prosthetic branch **252** and the prosthetic trunk **254**. The prosthetic branch **252** is preferably crimped (not shown), seamless and about 6 mm in diameter through its length. The prosthetic trunk **254** is seamless and about 12 mm in diameter through its length. The prosthetic branch **252** is anastomosed to the prosthetic trunk **254** between first **253** and second **255** proximal stents.

FIG. **12***b* is an external view of the prosthesis of FIG. **12***a*. As shown, only the top two stents **253**, **255** are attached externally to the prosthesis **250**. The other stents shown in FIG. **12***a* are attached internally. The stents **253**, **255** that are around the anastomosis **259** may be affixed internally so that they do not catch on guide wires (not shown) used in deployment of the prosthesis **250**. FIG. **12***c* shows a top view of the prosthesis of FIGS. **12***a* and **12***b*. The prosthetic branch **252** turns 137° around the prosthetic trunk **254**, and is attached to the prosthetic trunk **254** at a location **261**.

An external view of a peripheral branched prosthesis **300** is shown in FIG. **13***a*. The prosthetic trunk **302** and the prosthetic branch **304** are both preferably made from polyester. The prosthetic branch **304** is preferably crimped (not shown) and seamless. Z-stents **306** of both 14 mm and 22 mm amplitudes are preferably attached to the prosthesis **300** with sutures (not shown). Prolene® 5-0 is used to attach the internal distal stents **312**, shown in FIG. **13***b*; polyester 4-0 is used to attach the proximal stents **310**. There are preferably crimps **301** between the stents **306** of the prosthetic trunk **302**; these may increase flexibility and decrease kinking of the trunk **302**. Gold markers (not shown) may be employed. A nitinol ring or coil may be attached to the prosthetic trunk **302** above the Z-stents; a corresponding nitinol ring or coil is preferably attached to the distal section of the leg to which the peripheral branched prosthesis **300** can mate.

The prosthetic trunk **302** is preferably straight, having a consistent 12 mm diameter throughout. The stent **314** that abuts the prosthetic branch **302** has an amplitude of 22 mm, except as shown in FIG. **13***b* where the amplitude is 11 mm near the anastomosis **320**. This stent **314** is preferably attached externally, as shown; it may be affixed internally. The angle of incidence of the prosthetic branch **304** to the prosthetic trunk **302** at the anastomosis **320** can range from about 20° to about 60°, and is preferably about 45°; the skew relative to the longitudinal axis **324** is preferably between about 0° to about 20° and more preferably about 0°. The length of the prosthetic branch **304** is adjacent to the prosthetic trunk **302**; this may improve the distribution of material to reduce packing density during deployment of the prosthesis **300**. The prosthetic branch **304** is anchored to prosthetic trunk **302** about 4 mm from the anastomosis **320** using about three sutures; they may be affixed further away to ensure the flexibility of the anastomosis **320**.

The most proximal stent **322** is preferably of a 14 mm amplitude and attached externally to the prosthesis **300**. The material underneath the most proximal stent **322** is crimped for superior mating to a proximal prosthesis; this stent **322** may also be attached to the inside surface of the prosthesis **300**. The enlarged anastomosis **320** described above in reference to FIG. **5** is used to connect the prosthetic branch **304** to the prosthetic trunk **302**. The three distal stents **312** are attached internally.

FIG. **13***c* shows a top view of the prosthesis of FIGS. **13***a-b*. The prosthetic branch **304** preferably wraps about 150° around the prosthetic trunk **302**. The distal ostium **330** of the prosthetic branch **304** is preferably beveled about 30°.

FIGS. **14***a-b* show a prosthesis **350** that is similar to that described in reference to FIG. **13**. The prosthetic branch **352** is preferably made from crimped polyester fabric. The region under the proximal stent **358** is crimped. The anastomosis **354** is preferably enlarged, as described above in reference to FIG. **5**. The prosthetic branch **352** is skewed relative to the longitudinal axis **356** of the prosthesis **350** and has an angle of incidence preferably of about 30° to about 40°. The bevel of the prosthetic branch **352** is may be trimmed to provide greater clearance for the top stent **358**.

FIG. **15***a* shows a schematic representation of a bifurcated endoluminal prosthesis **400** implanted into an aneurysmal aorta **402**. An example of a bifurcated endoluminal prosthesis **400** is the Zenith® AAA stent graft (Cook Incorporated, Bloomington, Ind.). The prosthesis **400** extends into the iliac arteries **404**, **405**. One of the iliac limbs **407** forms a tromboning interconnection with an iliac extension **409**, which, in this context is the prosthetic trunk. The iliac extension (i.e. prosthetic trunk) **409** is anastomosed to a helical prosthetic branch **408**. The helical prosthetic branch **408** forms a tromboning interconnection with the hypogastric branch extension **410** which sits in the hypogastric artery **406**. The helical prosthetic branch **408** may also curve around the other side (posterior side) of the iliac extension **409**.

In FIG. **15***b*, there is a modular prosthesis that is similar to that shown in FIG. **15***a*. However, the iliac extension **409** of FIG. **15***b* is connected to the iliac leg **407** via an intervening prosthetic module **403**. An example of an intervening prosthetic module **413** is shown in FIG. **15***c*. The distal end **423** of the intervening prosthetic module **413** is crimped and has an internal stent **420**. External stents **422** are attached to the outside of the module **413**. The intervening prosthetic module

403 is preferably deployed after the aortic stent graft **400** and the iliac extension **409** are deployed, so that the intervening prosthetic module **403** is overlapped on both ends. The crimps on the distal end **423** preferably engage corresponding crimps on the proximal end of the iliac extension **409**. Either the aortic graft **400** or the iliac extension **409** may be deployed first.

It may be preferable to support the prosthetic branch with one or more stents. As shown in FIG. **16**, the prosthetic branch **414** has annular stents **415**. These stents **415** are preferably made of stainless steel, or nitinol wire or other shape memory metal. Any suitable thickness of wire may be used, preferably of a diameter of about 0.006-0.009 inch. The stents **415** can be either closed loop rings or coils with free ends, and can be attached using sutures or other suitable method. They can be positioned at various intervals from a location near the trunk **412** to the distal ostium **416**. FIG. **17** shows an annular stent **415** affixed to the distal ostium **416** of the branch prosthesis **414** using sutures **417**.

As shown in FIG. **18**, a helical stent **418** can also be used to support the helical branch **414**. The helical stent **418** is preferably made from nitinol or other shape memory metal. Any suitable thickness of wire may be used, preferably having an outer diameter of about 0.006-0.009 inch. As shown in FIG. **19**, an end of the helical stent **418** can be formed into a closed loop **419** so that it supports the distal ostium **416** of the branch **414**. FIG. **20** shows a nitinol coil that is attached to the proximal ostium of the branch **414** to hold the ostium in its operational state.

FIGS. **21***a-d* show two, preferably endless, Z-stents that have two regions: the zigzag region **437** which encircles the tubular graft and a section designed to accommodate and/or support at least a portion of the branch-trunk anastomosis. The stent of FIG. **21***a* has a section **438** that is shaped to support the proximal aspect of the anastomosis. The stent of FIG. **21***b* has a section **439** that is shaped to support the distal aspect of the anastomosis. The stents of FIGS. **21***a-b* are shown working to support a branch-trunk anastomosis in FIG. **22***a*.

As shown in FIG. **22***a*, the endless Z-stents are attached to the prosthetic trunk; each stent is curved around one of two different portions of a perimeter of the anastomosis. The stents of FIGS. **21***a* may also be placed on the distal aspect of the anastomosis, which the stent of FIG. **21***b* is placed on the proximal aspect of the anastomosis. FIG. **22***b* shows a stent similar to that shown in FIG. **21***c* attached to a stent graft.

FIG. **21***c* shows a Z-stent **437** that contains a loop **440** that is designed to follow the perimeter of the branch-trunk anastomosis. FIG. **21***d* has a section **441** that is shaped to support the distal aspect of the anastomosis.

FIGS. **23***a-d* show a stent that is designed to maintain the shape of the branch-trunk anastomosis. The stent **470** has three main portions, a distal hoop **472**, a proximal hoop **471** and an ovoid outer stent perimeter **473**. FIG. **23***e* shows the stent **470** attached internally to a branch-trunk anastomosis. The stent **470** may be attached in any conventional manner, including sutures. The ovoid outer perimeter **473** is preferably sutured to the prosthetic trunk, while the hoops **471**, **472** extend away from the perimeter **473** into the prosthetic branch, and is preferably sutured to the prosthetic branch. The stent **470** preferably maintains the shape of the anastomosis.

The stent of FIGS. **23***a-f* is preferably made from a single nitinol wire or similar shape-memory metal. To have the wire “remember” the shape depicted in FIGS. **23***a-e*, the wire is preferably heat-set while in that shape. This can be accomplished through the use of the device **474** of FIGS. **24***a-d* or a similar heat-setting fixture or mold. A plan view of the fixture

474 is shown in FIG. **24***b*. The ovoid outer perimeter **473** is formed by wrapping the nitinol wire around the column **486**. The distal hoop **472** is formed by looping the wire over the distal arch section **485** of the base **483**; the proximal hoop **471** is formed by looping the wire over the proximal arch section **484** of the base **483**. The hoops **471**, **472** kept in place by the arched surfaces **478**, **479** on the fixture cavity **481** when the fixture cavity **481** is attached to the base **483**. The base **483** is attached by a screw or bolt that passes through the hole **480** and into the column **486**.

For prosthetic trunks designed for implantation into the aorta, prosthetic branches may be formed to shunt flow into the superior mesenteric, celiac and both renal arteries. There are a variety of possible arrangements and orientations for these multiple branches, as shown in FIGS. **25** through **27**. FIG. **25** shows an aortic module **520** having two renal branches **524**, **525**, both of which shunt flow proximally relative to the prosthetic trunk. In FIG. **25**, both the celiac branch **522** and the SMA branch **521** shunt flow distally relative to the prosthetic trunk. As shown in FIG. **26**, the celiac branch **523** can be positioned so that it extends proximally.

As shown in FIG. **27***a*, the celiac branch **526** can extend distally from the same side of the trunk **520** as the SMA branch **521**. The renal branches can also be positioned so that they extend distally. FIG. **27***b* has helical renal branches **524**, **525** that extend proximally relative to the prosthetic trunk **520**. The celiac **533** and SMA **534** branches share a common anastomosis **519** before splitting to their respective vessels. FIG. **27***c* shows an arrangement for the renal branches **538**, **539** having a common anastomosis **535**.

In FIG. **27***d*, the prosthesis has celiac and SMA branches **533**, **534** in fluid communication with the prosthetic trunk **520** through a common anastomosis **519** formed in the wall of the prosthetic trunk. In this example, the celiac branch **533** is in fluid communication with the SMA branch **534** through an anastomosis **537** formed in the wall of the SMA branch. Thus, the celiac branch inlet end is separate, and disposed downstream, from the SMA branch inlet end.

One advantage of decoupling the inlet ends of the branches **533**, **534** is that the size of the trunk anastomosis **519** may be reduced. This may reduce the amount of graft material at the anastomosis **519** and the packing density of the graft within the delivery sheath. For example, two prostheses may be constructed, each having celiac and SMA branches **533**, **534** that share a common anastomosis **519**, as shown in FIG. **27***b*. In this example, the distal ends of the celiac and SMA branches **533**, **534** each have a diameter of 8 mm. In the first graft, the celiac and SMA branches **533**, **534** are constructed so that they bifurcate adjacent the anastomosis **519** into branches, each having a diameter of approximately 8 mm. The first graft is constructed with an anastomosis **519** that is large enough to accommodate the size of the inlet ends of both branches **533**, **534**, for example, approximately 16 mm.

The second graft is constructed with the inlet ends of the branches **533**, **534** decoupled as shown, for example, in FIGS. **27***d* and **27***e*. The anastomosis **519** need only be large enough to accommodate the inlet end of the SMA branch **534** and, therefore, it may be possible to construct the second graft with a substantially smaller anastomosis **519** without compromising fluid flow. For example, the second graft may have an anastomosis **519** with a diameter of approximately 10 mm. The diameter of the SMA branch **534** may taper along its length, as shown in FIG. **27***e*.

It should be understood that this example is illustrative, rather than limiting, and that the absolute and relative dimensions of the grafts and components of the grafts can vary. For example, the anastomosis **519** in the first graft described above may have a diameter that is less than or greater than 16 mm. Likewise, the anastomosis **519** in the second graft described above may have a diameter that is less than or greater than 10 mm.

At least one of the branches **533**, **534** may be disposed longitudinally along and circumferentially about the trunk **520**, as shown in FIGS. **27***b* and **27***d*. FIG. **27***e* shows an example of a prosthesis where the celiac branch **533** is disposed longitudinally along and circumferentially about the SMA branch **534**. The size, configuration, and orientation of the branches will be determined based on various considerations, as discussed throughout the specification, such as patient anatomy and promoting laminar flow.

Any of the branches can be oriented so that they extend proximally or distally; similarly, any of the branches can be positioned on either side of the trunk. The arrangements may be chosen in response to patient anatomy, as well as deployment and functional considerations.

FIG. **28***a* shows an internal helical branch **528**, extending circumferentially around and longitudinally about an internal surface of the prosthetic trunk **527**, terminating at the distal ostium **529**. As shown in FIG. **28***b*, this approach may cause turbulent flow, especially where the internal branch **528** is at an angle to the blood flow. To improve flow characteristics, the internal branch **528** can be straddled by baffles **530**, **531**, as shown in FIG. **29**. These baffles **530**, **531** may be made of any of the materials listed above, and function by filling in or covering the gaps **532** on either side of the branch **528**, where it contacts the trunk **527**. Baffles preferably act to deflect the flow around portions of the internal helical branch that are at an angle to the direction of blood flow, so that the blood flow is less turbulent.

Another solution to the turbulent flow around the internal branch **528** is the inclusion of the branch **528** within a pocket **536**, as shown in both FIGS. **30** and **31**. The cross-section depicted in FIG. **31** shows more laminar flow along the pocket **536** where the internal helical branch runs at an angle to the direction of blood flow. The pocket **536** may be made from woven polyester twill, as described above, or any other suitable material. The internal branch is preferably stented so that it remains patent. The stents may be similar to those stents described and shown in regard to external helical branches. An internal figure-8 Z-stent **535** shown in FIG. **28***c* may also be used to keep both the branch lumen **533** and the trunk lumen **534** patent. The figure-8 stent **535** is preferably made from a single length of stainless steel wire.

To facilitate deployment of a prosthetic extension module into a prosthetic branch, it may be necessary to have a preloaded wire extend from the inside of the main prosthesis through the prosthetic branch. Depending on the configuration of the prosthetic branch, such a wire may have to bend excessively (i.e., have a small radius bend) as it passes from the main body of the prosthesis into the prosthetic branch. This situation may cause damage to the wire or the prosthesis, or impede deployment. As shown in FIG. **32***a*, an enlarged anastomosis **541** between the prosthetic trunk **540** and prosthetic branch **545** may enable the deployment wire **543** to have a bend of a larger radius.

An enlarged anastomosis **541** of this type may be especially important in the side branch vessels of the aortic arch, including the left subclavian, left common carotid and innominate arteries. A helical branch **545** extending into the innominate artery, which has a tail section to accommodate the guide wire, is shown in FIG. **32***a*. The size of the anastomosis **541** may be measured relative to the radius of the prosthetic branch **545**. The radius of the anastomosis **541** may be twice that (or more) of the average radius of the prosthetic branch **545** or the distal ostium **546** of the branch **545**. The anastomosis **541** shown in FIG. **32***a* is enlarged by the addition of a tail section **542** through which the wire **543** can travel, which also increases the radius of the turn. An anastomosis with a tail section will be understood as being an anastomosis that has both a wide section and a narrow section, the narrow section being the tail. The thoracic aortic stent graft of FIG. **32***a* may also extend further into the abdominal aorta, having some of the branches and/or fenestrations described elsewhere in this application. The tailed anastomosis can also be used to increase the guidewire's turn radius in Y-shaped side branches.

FIGS. **32***b* and *c* show various arrangements for the thoracic side branches that extend from the prosthetic trunk **540**. The enlarged anastomosis shown in FIG. **32***a* may also be used in the thoracic prosthetic branches shown in FIGS. **32***b* and *c*. In FIG. **32***b*, there are separate helical side branches **547**, **567**, **569** for the innominate, left common carotid, and left subclavian, respectively. The arch grafts are preferably curved to accommodate the curve of the aortic arch. FIG. **32***c* shows the left common carotid prosthetic branch **551** and left subclavian prosthetic branch **553** having a common anastomosis **548**. Any of the branches shown in FIGS. **32***a-c* may be selectively replaced by fenestrations.

FIG. **32***c* has proximal strain relief crimps **579** and distal strain relief crimps **581** in the prosthetic trunk **540**. These are selectively placed on the ends of the prosthetic trunk **540** to provide some strain relief as the thoracic aorta undergoes axial compression and extension under the influence of pulsatile flow. The crimps **579**, **581** allow the graft to more easily lengthen, shorten and bend in tandem with the thoracic aorta. The distal **582** and proximal **583** stents improve sealing at the ends of the trunk **540**, and may also have barbs (not shown) to enhance fixation.

Blood flow to the various branch vessels of the aorta or other vessel may be accommodated through use of any combination of fenestrations and prosthetic branches, including the integral helical branches described above. One such combination is shown in FIGS. **33** through **40**. FIGS. **33** through **40** show various views of an endoluminal prosthesis **549** that has a helical prosthetic branch **552** for shunting flow to one of the renal arteries, a contralateral renal fenestration **558** (an aperture in the wall of the prosthesis that allows blood to flow to one of the renal arteries) and a superior mesenteric artery fenestration **556** (an aperture in the wall of the prosthesis that allows blood to flow to the SMA). A flareable covered or uncovered stent may be deployed into either or both fenestrations **556**, **558** in the manner described in U.S. patent application Ser. Nos. 10/984,040; 10/984,416; 10/984,417; 10/984,131; 10/984,520; and 10/984,167, all of which were filed on Nov. 8, 2004 and all of which are incorporated herein by reference.

FIG. **33** shows the helical branch **552** extending proximally along a tapered prosthetic trunk **550** relative to the prosthetic trunk **550**, i.e., away from the distal end **555** of the prosthesis **549**. As shown, the helical branch **552** has a pitch (or skew) of about 44° relative to the longitudinal axis of the prosthetic trunk **550** and is preferably attached with six evenly space sutures. The branch **552** is preferably not stretched or compressed when sutured to the trunk **550**. Radiopaque markers **557**, **559** are attached to both the trunk **550** and the branch **552**. The radiopaque markers **559** on the trunk **550** are preferably aligned with the longitudinal axis of the trunk **550**. A suprarenal stent **562** is located at the proximal end **562** of the prosthesis **549**; this stent is preferably a Z-stent having a diameter of 32 mm, a height of 25 mm and a period of 10. The SMA fenestration **556** is visible in FIG. **33**. A fenestration may also be provided for the celiac artery in addition to or instead of the SMA fenestration. The helical branch **552** is preferably crimped (not shown) to help resist kinking.

FIGS. **34** through **36** show the same device in different rotations. FIG. **34** shows the relative orientation of the renal fenestration **558** and the SMA fenestration **556**. The relative orientation of the branch and the fenestrations can be modified to suit a particular patient's anatomy. FIG. **35** shows the enlarged anastomosis **564** between the branch **552** and the trunk **550**. FIG. **36** shows the beveled ostium **565** of the branch **552**.

FIGS. **37** and **38** show skeletal views of the device depicted in FIGS. **33** through **36**; the distal internal stents **559** and proximal internal stents **560** are visible in these figures. The distal internal stents **559** are preferably Z-stents having a diameter of 24 mm, a height of 14 mm and a period **10**. The proximal internal stents **560** are preferably Z-stents having a diameter of 32 mm, a height of 22 mm and a period of 12. The outer stents **561** are preferably Z-stents having dual amplitude, a diameter of 32 mm, a height of 17 mm at a period of 11, and a height of 8.5 mm at a period of 22; these stents **561** are preferably made of nitinol wire having an outer diameter of about 0.330 mm. Any of these dimensions can be tailored to a particular patient's anatomy. FIG. **39** shows a view in the direction of arrow "A" shown in FIG. **38**; FIG. **40** shows a view in the direction of arrow "B" shown in FIG. **38**.

FIGS. **41***a-d* show different views of a stent graft **600** having a helical prosthetic branch **614** and three fenestrations: a left renal fenestration **606**, a right renal fenestration **636** and an auxiliary fenestration **604**. The helical branch **614** feeds the SMA and extends longitudinally and circumferentially from the enlarged anastomosis **622**. The proximal end **630** of the stent graft **600** also has a scallop **630** to accommodate the celiac artery. By combining one or more fenestrations with one or more helical branches, flow to one or more of the branch vessels may be preserved while optimizing the deployment characteristics of the stent graft system and packing profile of the stent graft within the deployment sheath.

Radiopaque markers **602**,**612** near the proximal **626** and distal **624** ends of the stent graft **600** help the surgeon identify the rotation of the stent graft **600** during deployment, as do the markers **620** on the helical branch **614**. The helical branch **614** may have a beveled distal anastomosis **618**. The stent graft **600** is supported by both externally placed stents **610** near the proximal end **626** of the stent graft **600** and internally placed stents **608**. As shown in FIG. **41***c*, regions **632**,**634** near the anastomosis **622** may be occupied by stents of any shape, preferably those designed to avoid obstructing and support the anastomosis **622**, such as those of FIGS. **21***a-d*. FIG. **41***d* shows an axial view of the stent graft **600** from the distal end **624**.

FIGS. **42***a-d* show another stent graft **650** that has both fenestrations and a helical branch graft. This stent graft **650** has a taper **670** in the middle such that the diameter is smaller at the distal end **656** and through the distal section **668** than at its proximal end **658** and through its proximal section **666**. There are three fenestrations in the graft, an SMA fenestration **662**, a left renal fenestration **664**, and a right renal fenestration **672**. The helical branch **660** provides flow to the celiac artery. The stent graft **650** is supported by external Z-stents **654** and internal Z-stents **676**. The taper **670** may by supported by stents of any shape, preferably those designed to avoid obstructing the branch-trunk anastomosis **670**, such as those of FIGS. **21***a-d*. There is an uncovered proximal stent **652** which preferably has barbs (not shown) extending from it to enhance fixation.

Since arterial anatomy and aneurysm topology vary between patients, any of the prosthesis designs described above is preferably modified to accommodate a particular patient's need. The first step is to review the patient's CT scans. The critical parameters for prosthesis design (deployment site, proximal and distal sealing points) for the device needed for each patient are defined. A three-dimensional (3-D) model of the aneurysm is created using techniques known to one of skill in the art.

The aneurysm model can be incorporated into Solid Works™ or other suitable solid and surface modeling software. With this software a 3-D endoluminal prosthesis can be designed based on the aneurysm model and the defined critical parameters. A mechanical drawing is developed from the 3-D device. The mechanical drawing specifications are then used to create the component materials for the prototype prosthesis, including the prosthesis fabric and stents. Then the material and stents are assembled to form the final prosthesis.

A Modular Prosthesis and Introducer

Modular prostheses are known for use in treating descending thoracic and abdominal aortic aneurysms, where the prosthesis at the proximal end defines a single lumen for placement within the aorta and at the other end is bifurcated for extension into the iliac arteries. Iliac extension prosthetic modules can be connected to the ends of the bifurcation. A schematic view of such a prosthesis is described in further detail in PCT application WO98/53761.

WO98/53761 discloses a prosthesis which includes a sleeve or tube of biocompatible prosthesis material such as polyester fabric or polytetrafluoroethylene (PTFE) defining a single-lumen portion and a bifurcation, and further includes several stents secured therealong. The prosthesis is designed to span an aneurysm that extends along the aorta proximally from the two iliac arteries. This reference also discloses the manner of deploying the stent prosthesis in the patient utilizing an introducer assembly.

In the WO98/53761 application, the material-covered portion of the single-lumen proximal end of the prosthesis bears against the wall of the aorta above the aneurysm to seal the aneurysm at a location that is spaced distally of the entrances to the renal arteries. Thin wire struts of a proximal attachment stent traverse the renal artery entrances without occluding them, while anchoring the prosthesis in position within the aorta.

An extension module is affixed to one of the legs of the prosthesis to extend along a respective iliac artery and, optionally, extensions may be affixed to both legs. These extension modules are attached by tromboning. The deployment of a modular endoluminal prosthesis into the lumen of a patient from a remote location by the use of a deployment device or introducer is disclosed in the same patent application. PCT application WO98/53761 is incorporated herein by reference.

One modular prosthesis similar to that described in WO98/53761, the Zenith® AM Endovascular Graft sold by Cook Incorporated, has been approved by the Food and Drug Administration (FDA) to treat aortic aneurysms. The Zenith® AAA Endovascular Graft is made up of three prosthetic modules: a main body module and two leg modules. The main body is positioned in the aorta. The legs are positioned in the iliac arteries and connect to the main body. The prosthesis thus extends from the aorta below the renal arteries into both iliac arteries. The prosthesis itself is made of a polyester material like that used in open surgical repair. Standard surgical suturing techniques are used to sew the graft material to a frame of stainless steel stents. These self-expanding stents provide support for the graft material.

FIG. **43** shows a Zenith® self-expanding bifurcated prosthesis **720** (product code TFB1 through TFB5, available from Cook Incorporated, Bloomington, Ind.), and an endovascular deployment system **700**, also known as an introducer **700**, for deploying the prosthesis **720** in a lumen of a patient during a medical procedure. These items are each described in greater detail in PCT application WO98/53761. A self-expanding branched prosthesis **750** similar to that described in reference to FIG. **13***b* is also shown.

The bifurcated prosthesis **720** has a generally inverted Y-shaped configuration. The prosthesis **720** includes a body **723**, a shorter leg **760** and a longer leg **732**. The bifurcated prosthesis **720** comprises a tubular graft material, such as polyester, with self-expanding stents **719** attached thereto. The self-expanding stents **719** cause the prosthesis **720** to expand following its release from the introducer **700**. The prosthesis **720** also includes a self-expanding Z-stent **721** that extends from its proximal end. The self-expanding Z-stent **721** has distally extending barbs **751**. When it is released from the introducer **700**, the self-expanding Z-stent **721** anchors the barbs **751**, and thus the proximal end of the prosthesis **720**, to the lumen of the patient. As an alternative to the prosthesis **720** shown in FIG. **43**, a prosthesis such as that shown in FIG. **6** could be deployed followed by renal branch extensions; this would have the added benefit of excluding any aneurysmal tissue in the renal arteries and allowing the aortic graft to extend further proximally. The self-expanding branched prosthesis **750** is similar to the branched prosthesis described in reference to FIG. **13***b* and is configured to form a tromboning connection with the shorter leg **760** of the bifurcated prosthesis **720** and with a branch extension. A notch or scallop may be cut into the proximal end of the branched prosthesis **750** to facilitate deployment of the module.

The introducer **700** includes an external manipulation section **780**, a distal attachment region **782** and a proximal attachment region **784**. The distal attachment region **782** and the proximal attachment region **784** secure the distal and proximal ends of the prosthesis **720**, respectively. During the medical procedure to deploy the prosthesis **720**, the distal and proximal attachment regions **782** and **784** will travel through the lumen to a desired deployment site. The external manipulation section **780**, which is acted upon by a user to manipulate the introducer, remains outside of the patient throughout the procedure.

The proximal attachment region **784** of the introducer **700** includes a cylindrical sleeve **710**. The cylindrical sleeve **710** has a long tapered flexible extension **711** extending from its proximal end. The flexible extension **711** has an internal longitudinal aperture (not shown). This longitudinal aperture facilitates advancement of the tapered flexible extension **711** along an insertion wire (not shown). The longitudinal aperture also provides a channel for the introduction of medical reagents. For example, it may be desirable to supply a contrast agent to allow angiography to be performed during placement and deployment phases of the medical procedure.

A thin walled metal tube **715** is fastened to the extension **711**. The thin walled metal tube **715** is flexible so that the introducer **700** can be advanced along a relatively tortuous vessel, such as a femoral artery, and so that the distal attachment region **782** can be longitudinally and rotationally manipulated. The thin walled metal tube **715** extends through the introducer **700** to the manipulation section **780**, terminating at a connection means **716**.

The connection means **716** is adapted to accept a syringe to facilitate the introduction of reagents into the thin walled metal tube **715**. The thin walled metal tube **715** is in fluid communication with the apertures **712** of the flexible extension **711**. Therefore, reagents introduced into connection means **716** will flow to and emanate from the apertures **712**.

A plastic tube **741** is coaxial with and radially outside of the thin walled metal tube **715**. The plastic tube **741** is "thick walled"—its wall is preferably several times thicker than that of the thin walled metal tube **715**. A sheath **730** is coaxial with and radially outside of the plastic tube **741**. The thick walled plastic tube **741** and the sheath **730** extend distally to the manipulation region **780**.

During the placement phase of the medical procedure, the prosthesis **720** is retained in a compressed condition by the sheath **730**. The sheath **730** extends distally to a gripping and hemostatic sealing means **735** of the external manipulation section **780**. During assembly of the introducer **700**, the sheath **730** is advanced over the cylindrical sleeve **710** of the proximal attachment region **784** while the prosthesis **720** is held in a compressed state by an external force. A distal attachment (retention) section **740** is coupled to the thick walled plastic tube **741**. The distal attachment section **740** retains a distal end **742** of the prosthesis **720** during the procedure. Likewise, the cylindrical sleeve **710** retains the self-expanding Z-stent **721**.

The distal end **742** of the prosthesis **720** is retained by the distal attachment section **740**. The distal end **742** of the prosthesis **720** has a loop (not shown) through which a distal trigger wire (not shown) extends. The distal trigger wire extends through an aperture (not shown) in the distal attachment section **740** into an annular region between the thin walled tube **715** and the thick walled tube **741**. The distal trigger wire extends through the annular space to the manipulation region **780**. The distal trigger wire exits the annular space at a distal wire release mechanism **725**.

The external manipulation section **780** includes a hemostatic sealing means **735**. The hemostatic sealing means **735** includes a hemostatic seal (not shown) and a side tube **729**. The hemostatic sealing means **735** also includes a clamping collar (not shown) that clamps the sheath **730** to the hemostatic seal, and a silicone seal ring (not shown) that forms a hemostatic seal around the thick walled plastic tube **741**. The side tube **729** facilitates the introduction of medical reagents between the thick walled tube **741** and the sheath **730**.

A proximal portion of the external manipulation section **780** includes a release wire actuation section that has a body **736**. The body **736** is mounted onto the thick walled plastic tube **741**. The thin walled tube **715** passes through the body **736**. The distal wire release mechanism **725** and the proximal wire release mechanism **724** are mounted for slidable movement onto the body **736**.

The positioning of the proximal and distal wire release mechanisms **724** and **725** is such that the proximal wire release mechanism **724** must be moved before the distal wire release mechanism **725** can be moved. Therefore, the distal end **742** of the prosthesis **720** cannot be released until the self-expanding Z-stent **721** has been released, and the barbs **751** have been anchored to the lumen. Clamping screws **737** prevent inadvertent early release of the prosthesis **720**. A hemostatic seal (not shown) is included so that the release wires can extend out through the body **736** without unnecessary blood loss during the medical procedure.

A distal portion of the external manipulation section **780** includes a pin vise **739**. The pin vise **739** is mounted onto the distal end of the body **736**. The pin vise **739** has a screw cap **746**. When screwed in, vise jaws (not shown) of the pin vise **739** clamp against or engage the thin walled metal tube **715**. When the vise jaws are engaged, the thin walled tube **715** can only move with the body **736**, and hence the thin walled tube **715** can only move with the thick walled tube **741**. With the screw cap **746** tightened, the entire assembly can be moved together as one piece.

A second introducer may be used to introduce the helical branched prosthesis **750** and create a tromboning connection. This second introducer may be based on the same principles as the introducer **700** described above, but could be less complex. For example, the second introducer may include a sheath for containing the branched prosthesis **750** in a compressed state, so that it can be introduced into a targeted anatomy and then released to either self-expand or be actively expanded with a balloon. The second introducer could be equipped with a delivery tip **800**, as shown in FIG. **44**, to allow for the deployment of a guide wire **802** into the aortic bifurcation. A third introducer may be used to deploy the branch extension.

Deployment

Prosthetic modules are preferably deployed seriatim. The intermodular connection between the branched prosthesis **750** and the bifurcated prosthesis **720** is formed in situ. First the bifurcated prosthesis **720** is deployed, and then the branched prosthesis **750** is deployed. For example, a bifurcated aortic prosthesis **720**, as described in WO98/53761, can be deployed into the abdominal aorta. The bifurcated prosthesis **720** has a generally inverted Y-shaped configuration having a body portion **723**, a shorter leg **760** and a longer leg **732**. The body of the prosthesis is constructed from tubular woven polyester fabric. At the proximal end of the prosthesis **720** is a self-expanding stent **721** which extends beyond the end of the prosthesis and has distally extending barbs **751**. The shorter leg **760** and the longer leg **732** have internal projections extending from their distal termini.

This bifurcated prosthesis **720** can be deployed in any method known in the art, preferably the method described in WO98/53761 in which the device is inserted by an introducer via a surgical cut-down into a femoral artery, and then advanced into the desired position over a stiff wire guide using endoluminal interventional techniques. For example, a guide wire (not shown) is first introduced into a femoral artery of the patient and advanced until its tip is beyond the desired deployment region of the prosthesis **720**. At this stage, the introducer assembly **700** is fully assembled, and ready for introduction into the patient. The prosthesis **720** is retained at one end by the cylindrical sleeve **710** and the other by the distal attachment sections **740**, and compressed by the sheath **730**. If an aortic aneurism is to be repaired, the introducer assembly **700** can be inserted through a femoral artery over the guide wire, and positioned by radiographic techniques, which are not discussed here.

Once the introducer assembly **700** is in the desired deployment position, the sheath **730** is withdrawn to just proximal of the distal attachment section **740**. This action releases the middle portion of the prosthesis **720** so that it can expand radially. The proximal self-expanding stent **721**, however, is still retained within the cylindrical sleeve **710**. Also, the distal end **742** of the prosthesis **720** is still retained within the external sheath **730**.

Next, the pin vise **739** is released to allow small movements of the thin walled tube **715** with respect to the thick walled tube **741**. These movements allow the prosthesis **720** to be lengthened or shortened or rotated or compressed for accurate placement in the desired location within the lumen. Radiopaque markers (not shown) may be placed along the prosthesis **720** to assist with placement of the prosthesis.

When the proximal end of the prosthesis **720** is in place, the proximal trigger wire is withdrawn by distal movement of the proximal wire release mechanism **724**. The proximal wire release mechanism **724** and the proximal trigger wire can be completely removed by passing the proximal wire release mechanism **724** over the pin vise **739**, the screw cap **746**, and the connection means **716**.

Next, the screw cap **746** of the pin vise **739** is then loosened. After this loosening, the thin walled tube **715** can be pushed in a proximal direction to move the cylindrical sleeve **710** in a proximal direction. When the cylindrical sleeve **710** no longer surrounds the self-expanding stent **721**, the self-expanding stent **721** expands. When the self-expanding stent **721** expands, the barbs **751** grip the walls of the lumen to hold the proximal end of the prosthesis **720** in place. From this stage on, the proximal end of the prosthesis **720** cannot be moved again.

Once the proximal end of the prosthesis **720** is anchored, the external sheath **730** is withdrawn to distal of the distal attachment section **740**. This withdrawal allows the contralateral limb **760** and the longer leg **732** of the prosthesis **720** to expand. At this point, the distal end **742** of the prosthesis **720** may still be moved. Consequently, the prosthesis **720** can still be rotated or lengthened or shortened for accurate positioning. Such positioning of the prosthesis **720** may ensure that the shorter leg **760** extends in the direction of a contralateral artery.

After the shorter leg **760** extends in the direction of the contra-iliac artery, the branched prosthesis **750** is deployed. The branched prosthesis **750** is deployed such that it forms a tromboning connection with the shorter leg **760** and extends from the shorter leg **760** into the contralateral artery. The coupling of the prosthesis **720** and branched prosthesis **750** is described in greater detail in other portions of this disclosure.

The method of introduction of the branched prosthetic module **750** may be as follows. A guide wire (not shown) is introduced into the contralateral femoral artery and advanced until its tip is above the region into which the prosthesis is to be deployed. The second introducer is then advanced over the guide wire with an oscillating and rotating action until the extension prosthesis is overlapped one full stent within the contralateral limb **760**. A final position check may then be made before the sheath is withdrawn while holding the thick walled tube in place. A similar methodology for deployment of a hypogastric branch graft module is described and illustrated in a U.S. Patent Application Publication No. 2005/0182476, which is incorporated herein by reference.

The guide wire **602** can be deployed from the tip **600** of the second introducer captured and pulled over to the ipsilateral side to facilitate deployment of a third introducer through the ipsilateral side into the contralateral side to deploy a branch extension into the hypogastric artery. Preferably, a preloaded wire or snare within the limb of the prosthetic branch will preclude the need for complex localization, catheterization of branches and separate insertion of the wire through the sheath. This approach may be particularly important when multiple branches are present. The distal handle of the delivery system may be equipped with an additional trigger wire to accommodate this feature. The second and third introducers and the methods of using them are described in greater detail in U.S. Patent Application, "Introducer for an Iliac Side Branch Device," Ser. No. 60/510,823, filed Oct. 14, 2003, which is incorporated herein by reference.

The introducer and deployment method described above can be adapted for implantation in other regions. For example, if a first prosthetic module is placed into the aorta, a connecting prosthetic module can be placed into the renal, iliac, superior mesenteric, celiac or other artery to form a tromboning interconnection. If a first prosthetic module is placed into the thoracic aorta, a connecting prosthetic module can be placed into another portion of the thoracic aorta, the left subclavian, left common carotid, innominate or other artery. Furthermore, prosthetic modules which are implanted in the same artery can be connected to each other. The overlap region of each of these embodiments is preferably adapted to the size of the relevant anatomy and the forces to which the prostheses are exposed in the relevant anatomy.

EXAMPLE 1

The flow force on the branched limb is dependent upon the loads applied to the branch point and ultimate angulation of the prosthetic branch. Of particular interest are the forces that may cause separation of the branch extension from the prosthetic branch. Forces due to flow in the y-direction, if significant enough, can become larger than the frictional forces that hold the branch extension and the prosthetic branch together, resulting in separation. If the separation is substantial, a type III endoleak will occur and the aneurysm will no longer be excluded.

The prostheses described above may be subjected to an in vitro leak pressure test. The purpose of this test procedure is to determine the minimum internal pressure required causing leakage at the mating point between two prostheses.

The test requires a pressure transducer, a pressure monitor, water/glycerin mixture (dyed)@3.64 cP, water bath, submersible heater, water pump, temperature controller, mating surface thermocouple, and mercury thermometer.

The prosthetic branch and branch extension are mated such that there is a suitable tromboning connection, preferably with a 1.5-2 cm overlap and a 1 mm or less difference in diameter at the interconnection. The devices may be ballooned for 30 seconds using a suitably sized balloon dilation catheter.

Internal pressure in the mated devices is measured utilizing a pressure transducer and pressure monitor. These instruments are connected to a syringe providing manually controlled pressure into the mated devices. The pressure liquid is a glycerin/water mixture to 3.64 centipoise (cP) dyed with blue food coloring. The device was placed in a 37° C. water bath and the presence of a leak would be defined and identified by leakage of the blue-dyed glycerin/water mixture. Visual accounts of leakage and a recording of peak pressures were manually recorded.

EXAMPLE 2

The prostheses described above may be subjected to an in vivo test, preferably in non-human mammals. One animal that is suitable for implantation of the prosthesis for testing and therapeutic purposes is the domestic cow. For testing purposes, six- to ten-week-old male calves were used.

As presurgical preparation, each animal was given a daily dose of 325 mg of aspirin beginning on the day prior to the procedure for the purpose of platelet inhibition. Each animal was kept without food for approximately 8-12 hours and without water for approximately 2 hours preceding each procedure. A pre-operative baseline ACT was measured in a Hemochron Jr. Signature Series Machine® (available from ITC in Edison, N.J.).

Each calf was sedated with Xylazine (1.0 mg/10 lbs, IM). Once the animal was lightly sedated, an induction mask was used to deliver Isofluorane (2-4%). The calf's face was placed into the mask while the inhalation anaesthetic was delivered.

The animal may be intubated in standard fashion. Once the endotracheal tube was placed, it was secured. The ventilator was turned on and connected to the animal to increase the depth of anesthesia and mechanically ventilate the animals. Isofluorane dosages ranged from approximately 0.8-1.25%, although may be any percentage based on relevant factors. During this pre-surgical preparation, each animal may also receive an injection of benzathine procaine penicillin (30,000-50,000 U/kg IM).

The animal was placed on its left side with its right hind leg extended up and secured with gauze ties. A ground pad and EKG leads were placed on the animal. An intravenous catheter (IV) was placed in the peripheral leg vein and secured with tape. Lactate Ringers (LR) was infused through the catheter for the duration of the procedure to provide adequate hydration. Both groins were shaved and sterilely prepped with 70% alcohol and betadine.

The implantation of this branched vessel device involved basic endovascular techniques. A femoral cutdown was performed on the left leg to gain access to a femoral vessel. A retroperitoneal incision was performed to provide access to the right iliac artery. A third access point was gained via a cutdown exposing the right carotid artery. Hemostatic vessel loops were placed proximally and distally on the arteries. A single wall puncture needle was used to access the left femoral artery, and conformation of the cannulation was confirmed by the presence of pulsatile arterial flow from the needle hub.

Once the pulsatile flow was observed, a wire was placed in the descending abdominal aorta. The animal was heparinized with 200 IU of porcine heparin/kg. An activated clotting time was obtained within 3-10 minutes following heparin administration to ensure adequate anti-coagulation, to achieve a preferred minimum of 1.5-2 times the baseline ACT. An 8 French introducer sheath was advanced into the left arterial lumen. Before and after placement, the side port of each sheath was flushed with 0.9% normal saline.

A 5 French pigtail catheter was inserted over the wire through the introducer sheath and advanced into to the region of the aortic arch using fluoroscopic guidance. A baseline digital subtraction angiogram of the descending thoracic aorta was obtained utilizing an appropriate dose of contrast. Once the baseline angiogram had been achieved, a wire was placed through the pigtail catheter and advanced into the thoracic aorta. The catheter was then removed. A 12.5 MHz Boston Scientific IVUS (intravenous ultrasound) probe was inserted over the wire in a monorail fashion, and baseline IVUS measurements were obtained. These measurements included cross-sectional diameters of the distal abdominal aorta approximately 9 cm proximal to the trifurcation.

An external helical device similar to that shown in and described in reference to FIG. **11** was employed. This particular prosthesis was manufactured from a Viabahn® Endoprosthesis (W. L. Gore & Associates, Inc., Newark, Del.), which is made from expanded PTFE. It was loaded into an 18 French cartridge with a 4 French catheter providing 0.035 inch wire access through the man device and a preloaded 0.018 inch wire within the branched limb.

A single wall puncture needle was used to access the right iliac artery. Once an Amplatz guide wire was placed, a 20 French Check-Flo® (Cook Incorporated, Bloomington, Ind.) introducer sheath was advanced to 9 cm above the aortic bifurcation and utilized as the delivery system. The preloaded 0.018 inch wire was advanced through the valve of the Check-Flo® sheath using a peal-away sheath. The loaded device cartridge was then inserted into the 20 French Check-Flo® using the dilators as pushers. The 0.018 inch wire was snared from the carotid artery to provide through-and-through access for the branch vessel wire. The prosthesis was then deployed to the point that the ostium of the prosthetic branch was exposed. The prosthesis was then advanced through the contralateral femoral artery.

The prosthesis was deployed with a 2.0 cm overlap within the prosthetic branch. The entire length of the prosthesis was ballooned with a 7 mm×4 cm balloon. Post implant angiographic and IVUS assessments were performed. The final IVUS assessment measured the proximal, mid and distal points of the stent graft along with the ostium, while the angiogram assessed the presence of any endoleaks, as well as the location of the stent graft. If desirable, the prosthesis may be explanted and subjected to post-explant analysis.

EXAMPLE 3

One helical branch vessel stent graft is deployed such that the branch is properly oriented with respect to the internal iliac artery. Four markers on the distal end of the branch are placed approximately 5 mm above the internal iliac artery. The sheath housing the device is withdrawn to expose the branch limb, leaving the distal end constrained within the sheath in the external iliac artery. The wire dwelling within the contralateral limb is replaced with a steerable guidewire, which is then advanced into the distal aorta and snared with a snare device introduced from the contralateral femoral artery. This provides access from the contralateral groin, through the proximal aspect of the iliac branch, into the iliac limb, and then alongside the outer portion of the distal segment (external iliac artery segment) to the ipsilateral groin.

Over this through-and-through wire, a 10 F or 12 F Balkin sheath (Cook Incorporated, Bloomington, Ind.) is introduced and advanced into the side branch limb. Alongside the through-and-through guidewire, a steerable catheter and wire combination is advanced and utilized to selectively cannulate the internal iliac artery.

Once a reasonable purchase is established, a stiffer wire is placed and the mating component is advanced into the desired position. The mating component may be a Viabahn® graft which is advanced into the hypogastric artery so that it has preferably a 2 cm minimum overlap with the helical branch. Once the mating graft is deployed and appropriately ballooned, the remainder of the external iliac limb is deployed. The component is then mated to the remainder of the Zenith® graft with the modified 12 mm extension described in FIG. **3***c*.

Although the invention has been described and illustrated with reference to specific illustrative embodiments thereof, it is not intended that the invention be limited to those illustrative embodiments. Those skilled in the art will recognize that variations and modifications can be made without departing from the true scope and spirit of the invention as defined by the claims that follow. It is therefore intended to include within the invention all such variations and modifications as fall within the scope of the appended claims and equivalents thereof.

The invention claimed is:

1. An endoluminal prosthesis comprising:

a prosthetic trunk having a first end and a second end and comprising a trunk lumen extending therethrough, a wall, and an anastomosis in the wall between the first and second ends;

a stent attached to the prosthetic trunk adjacent the anastomosis, where the stent comprises a generally tubular stent body that provides radial support to the prosthetic trunk, where the stent body alternates endlessly about a longitudinal axis of the prosthetic trunk between a first stent pattern and a second stent pattern;

where the first stent pattern comprises a loop having a contour that contacts and supports the entire perimeter of the anastomosis.

2. The prosthesis of claim **1**, where the second stent pattern has a generally zigzag shape.

3. The prosthesis of claim **1**, where the loop comprises an ovoid shape.

4. An endoluminal prosthesis comprising:

a prosthetic trunk comprising a trunk lumen extending therethrough;

a prosthetic branch comprising a branch lumen extending therethrough;

a stent having a stent pattern that alternates endlessly about the perimeter of the stent between a first tubular stent region disposed about a first axis and a second tubular stent region disposed about a second axis;

where the first stent region is attached to and supports at least a portion of the prosthetic trunk and the second stent region is attached to and supports at least a portion of the prosthetic branch, and

where the stent has a figure-8 shape.

5. The prosthesis of claim **4**, where the stent pattern includes a generally zigzag shape.

6. The prosthesis of claim **4**, where the first stent region has a different diameter than the second stent region.

7. The prosthesis of claim **4**, where the first stent axis is generally collinear with the second stent axis.

8. The prosthesis of claim **4**, where the prosthetic branch is disposed, at least in part, inside the prosthetic trunk lumen.

9. The prosthesis of claim **4**, where the prosthetic branch is disposed, at least in part, outside the prosthetic trunk lumen.

10. The prosthesis of claim **4** where at least a portion of the first stent region is disposed on an interior surface of the prosthetic trunk.

11. The prosthesis of claim **10**, where at least a portion of the first stent region is disposed on an exterior surface of the prosthetic branch.

12. The prosthesis of claim **4**, where at least a portion of the second stent region is disposed on an exterior surface of the prosthetic branch.

13. The prosthesis of claim **4**, further comprising any two or more of the following:

the stent pattern includes a generally zigzag shape;

the first stent region has a different diameter than the second stent region;

the first stent axis is generally collinear with the second stent axis;

the prosthetic branch is disposed, at least in part, inside the prosthetic trunk lumen;

the prosthetic branch is disposed, at least in part, outside the prosthetic trunk lumen;

the stent has a figure-8 shape;

at least a portion of the first stent region is disposed on an interior surface of the prosthetic trunk;

at least a portion of the first stent region is disposed on an exterior surface of the prosthetic branch; and

at least a portion of the second stent region is disposed on an exterior surface of the prosthetic branch.

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